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WITNESS my hand this
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J. Billingsley

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

IMPROVED BLOOD PUMP COMPRISING POLYMERIC COMPONENTS

Field of Invention

The present invention relates to an improved implantable blood pump comprising polymeric components and a process relating to construction of said polymeric components.

Background

Cardiovascular disease remains a leading cause of death in the developed world, responsible for more than 40% of deaths in Australia and in the United States. Annual diagnoses of new cases of heart failure in the United States have reached 550,000, leading to a population of approximately 4.7 million people afflicted by the disease; annual cost estimates for heart failure treatment range from USD$10 billion to $38 billion. Cardiac transplantation provides substantial benefit for patients with severe heart failure, however there is a gross disparity between the numbers of potential recipients (800,000 p.a. worldwide) and suitable transplant donors, approximately 3,000 p.a. worldwide. Consequently there is a clear need for development of an effective heart support device.

In the past, Ventricular Assist Systems ('VASs') have been developed to provide support to the heart and are typically used for temporary (bridge-to-transplant and bridge-to-recovery) and permanent (destination therapy) support of patients. Generally, support for the left ventricle with an assist device (rather than a total artificial heart) is sufficient to restore cardiovascular function to normal levels for patients with congestive heart failure. As a consequence of the shortage of transplants, there is a focus on long-term alternative-to-transplant support in device development. Earlier design VASs developed were pulsatile (implanted and external to the body). These designs and later ones of rotary blood pumps have demonstrated enhanced survival and quality of life for patients with end-stage heart failure compared with maximal medical therapy. However these devices may be large, cumbersome, inefficient, prone to mechanical failure and costly.

Additionally, recent evidence suggests that early intervention with mechanical support for the heart using a VAS can enable recovery of the myocardium, to the extent that the VAS can be removed. VASs have the potential to provide the patients with a far better quality of life than any previously available options.

It has been noted that continuous flow rotary VASs are inherently simpler, smaller and more reliable, as well as cheaper to produce, than the original pulsatile systems. For this reason, continuous flow centrifugal devices, such as the VentrAssist™ LVAS, have emerged as the definitive forms of technology in the field of cardiac assistance.

Previously, VentrAssist™ LVASs were fabricated from Titanium-6 Aluminium-4 Vanadium (Ti-6A1-4V) coated with amorphous carbon and/or diamond-like coatings. The inventions relating to the VentrAssist™ LVAS have been disclosed in US Patents 6227797, 6250550 & 6609883. One disadvantage of this LVAS is that the manufacturing cost is relatively high and complexity of milling

Ti-6Al-4V is also relatively high. It may be therefore desirable to manufacture the VentrAssist™ LVASs from a cheaper and easier to manufacture material.

In the past, several LVASs have been developed from cheaper and easier to manufacture material such as polymeric components. However, the main limitation is that a these prior art devices, are only suitable for short term use during surgery and as such are not suitable for implantable use. US Patents 4984972 & 5713730 disclose heart assist devices that include a housing made of polymeric material. These devices are not suitable for implantation and typically are used for short-term purposes.

Heart assist devices that include components made of polymeric material are known, but none of these are rotary blood pumps. Examples of a non-rotary implantable blood pumps are described in US Patents 6001056 and 5300111. However, rotary heart assist devices are the preferred device for implantable use as rotary blood pumps generally reduce haemolysis and thrombogenesis; and increase safety and reliability.

Some prior art blood pumps have been constructed using polymeric materials for non-moving components such as the outlet or nozzle of the pump. An example of such prior art pump is disclosed in US patent 5275580. The majority of the housing and impeller in

this pump is machined or fashioned out of metal, which substantially increase the cost of manufacture and complicates the manufacturing process.

The object of the present invention is aimed at providing an implantable rotary blood pump that ameliorate one or more of the abovementioned disadvantages.

Summary of the Invention

According to a first aspect the present invention consists in an implantable rotary blood pump including an impeller rotatable within a housing by an electric motor, characterised in that at least a portion of said impeller is made of a polymeric material.

Preferably said impeller includes at least one permanent magnet at least partially embedded within said polymeric material; and a barrier is disposed between said polymeric material and said magnet.

Preferably said barrier is a layer of non-biotoxic material.

Preferably said non-biotoxic material is any one of a metal, metallic compound or Parylene™.

Preferably at least one surface of said impeller is made of said polymeric material and said surface is subjected to ion deposition and/or implantation. Preferably said ion deposition and/or implantation occur in a gas plasma environment. Preferably the gas in said gas plasma environment is any of hydrogen, argon, helium, oxygen, nitrogen, methane or a hydrocarbon gas.

Preferably said surface is partially coated with carbon.

Preferably said surface is at least partially coated with a diamond-like coating.

Preferably said polymeric material includes polyetheretherketone.

Preferably at least a portion of said housing is made of polymeric material.

Preferably said polymeric material includes a pharmaceutical or similar chemical agent. Preferably said pharmaceutical or similar chemical agent is slowly released or eluted. Preferably said agent is an anti-coagulant and/or antimicrobial agent.

Preferably said polymeric material is coated with a polymer phospholipid or a metal.

Preferably said impeller or housing are constructed by injection moulding.

Preferably said impeller is suspended within said housing by hydrodynamic thrust forces generated by relative movement between said impeller and said housing and said impeller having a hydrodynamic bearing.

According to a second aspect the present invention consists in a method of treatment of polymeric components for use in an implantable rotary blood pump, said method comprising the steps of:

charging an electrode to attract ions from a plasma; and

said polymeric component positioned relative to said plasma and said electrode so as to create ion implantation of at least a region on the surface of said polymeric component.

Preferably during step (ii) said polymeric component is rotated to allow ion implantation to take place on substantially all surfaces of the polymeric component.

Preferably said electrode includes a mesh configuration, which includes a plurality of holes.

Preferably said mesh configuration is rotated to allow relatively even ion implantation through positional movement of the said holes with respect to the polymeric component.

Preferably at least a portion of said polymeric component is positioned between said plasma and said electrode.

Preferably said electrode includes a thin metal layer deposited over the outer surfaces of said polymeric component. Preferably said thin layer is deposited by sputtering or vacuum evaporation techniques.

Preferably said plasma is within a gas plasma environment. Preferably the gas of said gas plasma environment includes any of hydrogen, argon, helium, oxygen, nitrogen, methane or hydrocarbon gas.

Preferably said treated polymer component includes chemically modified polymers.

Brief Description of Drawings

Embodiments of the invention will now be described with reference to the drawings in which:

Figure 1 is a perspective side view of a first preferred embodiment of the present invention;

Figure 2 is an exploded schematic cross sectional view of a second preferred embodiment of the present invention; and

Figure 3 is a schematic cross-sectional view of a third preferred embodiment of the present invention;

Figure 4 is a schematic cross-sectional view of a fourth preferred embodiment of the present invention;

Figure 5 is a view of a first preferred impeller that may be included within an embodiment of the present invention;

Figure 6 is a perspective view of a second preferred impeller that may be included within an embodiment of the present invention;

Figure 7 is a perspective view of a third preferred impeller that may be included within an embodiment of the present invention;

Figure 8 is a schematic cross sectional view of a preferred blade of the impeller shown in figure 5;

Figure 9 is schematic illustration of a preferred method of ion implantation;

Figure 10 is a schematic illustration of a further preferred method of ion implantation; and

Figure 11 is a schematic illustration of a further preferred method of ion implantation;

Figure 12 is a graphical representation of a method of applying a charge to improve ion implantation;

Figure 12 is a graphical representation of a further method of applying a charge to improve ion implantation;

Figure 14 is a schematic illustration of a further preferred method of ion implantation; and

Figure 15 is a schematic illustration of a further preferred method of ion implantation.

Best mode of carrying out Invention

Figure 1 shows an implantable left "ventricle assist device" (VAD) adapted to pump by a centrifugal flow method, in accordance with a first embodiment of the present invention. An impeller 5 made of a polymeric material is positioned within a housing also made of a polymeric material. The housing comprises of an upper housing 4 and a lower housing 6. The upper housing 4 and the lower housing 6 may be preferably welded together and/or screwed together using screws 7. However, alternate securing means may be used to secure the upper housing 4 to the lower housing 6. The upper housing 4 and the lower housing 7 may be secured together by ultrasonic welding, laser welding, thermal welding, gluing and/or other physical securing means. The generally preferred securing means, in the case of securing components made of polymeric material, is welding.

In this embodiment, an upper stator assembly 3 and lower stator assembly 8 are preferably mounted outside of the housings in a radial/axial hybrid formation resulting in a mixed flow, or diagonal flow type pump. These stator assemblies comprise a series of electro-magnetic coils housed within an insulated housing. Mounted on each of the stator assemblies 3 and 8 are yokes. Only the upper yoke 10 is visible in Figure 1. These yokes

serve to assist the flow of EMF flux around the stator assemblies 3 and 8. These yokes are preferably constructed of a material capable assisting EMF flux.

Also in this first embodiment, the impeller 5 includes four blades 16 which are joined to each other in a generally circular arrangement, by bridging portions 15. Each one of the blades 16 additionally encloses a permanent magnet 17. This magnet 17 is preferably arranged to align at an angle of 22½° away from the axial orientation. The bridging portions 15 and/or blades 16 may preferably be constructed of polymeric material. Please note that the magnets may be aligned at any angle between 0° and 45° degrees.

This arrangement may allow the preferred blood pump to be axial-radial flow hybrid pump, although other pumping systems may be used. These other pumping systems include: radial and/or axial.

Covering the afore-described embodiment is a housing assembly comprising of an upper shroud 2 and a lower shroud 9. These shroud components are fixably attached together to seal the interior of this device from external fluids (eg. blood).

A further modification may be possible to this embodiment. This modification may include the addition of two flanges 11 and 12 protruding from an outer edge of the upper housing 4 and an outer edge of the lower housing 6, respectively. These flanges 11 and 12 are used to join the upper and lower housings 4 & 6. This attachment is preferably achieved by ultrasonic or laser welding.

Alternate securing means to attach the components of this embodiment and the case components may also include snap locks and/or adhesive bonding.

Additionally, the upper shroud 2 and lower shroud 9 may be ultrasonically welded by the connection of an additional two flanges 13 and 14. These flanges 13 and 14 both extend from an outer surface of the upper shroud 2 and an outer surface of the lower shroud 9, respectively. Preferably, flanges 13 and 14 may extend in a L-shape to allow joining of these flanges around flanges 11 and 12. Alternately, all of the flanges of the preferred embodiment may be sandwiched together so that flange 14 is attached to flange 11, flange 11 then is attached to flange 12 which is in turn attached to flange 13. This attachment may be achieved by ultrasonic or laser welding.

The aforementioned flanges 11, 12, 13 and 14 may also extend around the entire perimeter of the outer surface of the respective housing or shroud.

Preferably, a mounting lug 1 may be adapted to enable the device to be secured the circulatory system of the patient and/or stenting cannulae. The mounting lug 1 may incorporate a quick attachment means or a snap connection to facilitate a relatively quick installation.

Alternatively, the mounting lug 1 may be adapted to mate with a cannula for long term purposes or short term purposes which allow the pump device to be replaced.

Preferably, the pumping action of this embodiment, when in use, is driven by the forced vortex generated by the rotational motion of the impeller 5. The impeller 5 is driven magnetically through magnets 17 embedded within the blades 16 of the impeller 5 interacting with the upper 3 and lower 8 stator assemblies. Controlled and regulated electronic pulses are sent to the stator assemblies 3 and 8 and this in turn induces a current in the embedded electromagnets. The coils apply EMF force to the impeller 5, and this EMF force causes the impeller 5 to turn.

When in use, the impeller 5 of this embodiment is suspended within the housing using hydrodynamic thrust forces generated by the interaction of the edges of blades 16, the inner surfaces of the housing and the fluid flow.

Preferably in this embodiment, the lug 1, the upper shroud 2, the outer surface of upper stator assembly 3, the outer surface of lower stator assembly 8, the outer surface of the impeller 5, the upper housing 4, the lower housing 6, flanges 11, 12, 13, 14 and/or the lower shroud 9 may be constructed of polymeric materials. In doing so, they gain at least some of the aforementioned advantages of constructing a blood pump from polymeric components.

It is preferred to construct this embodiment from a substantial amount of polymeric components or partially polymeric components that will function safely and reliably. The preferred embodiment shown in Figure 1 may be constructed entirely from polymeric components except for components requiring electrical or magnetic conductivity. These

components may include the coils within the stator assemblies 3 and 8 and the magnets preferably embedded within the impeller 5.

The first embodiment of this invention is an axial/radial hybrid flow blood pump but the present invention may also apply to other various types of pumps including, but not limited to, axial flow or mixed flow blood pumps.

A further embodiment of the present invention is shown in Figure 2. In this embodiment, an implantable blood pump is shown comprising an inlet 22 and an outlet 25. An impeller 24 is positioned within an upper housing 18 and a lower housing 19. The impeller 24, upper housing 18 and lower housing 19 are all preferably made of a polymeric material. When in use, the impeller 18 is magnetically urged to rotate by the upper and lower stator assemblies 21 and 20, in a similar way to the earlier embodiment described in this specification. These stator assemblies preferably include yoke devices to aid in the flow of EMF flux around the stator assemblies.

Preferably this embodiment includes housings 18 and 19 that also function as the outer shroud for the device. The respective stator assemblies may be integrally moulded within the respective housings. Lugs 23 may be attached to the inlet and outlet of the pump and adapted to allow the device to be secured to either the circulatory system of the patient or to cannulae.

This embodiment preferably has impeller 24 suspended, in use, by a hydrodynamic bearing. In this embodiment, the impeller 24 does not touch the housings 18, 19 during its operation. This feature may significantly reduce the level and amount of wear and degradation of the main pump components. Thromboembolic complications may be also minimised by the incorporation of a shaftless rotating impeller. This preferred embodiment may also include a relatively small running clearance between the impeller blades and the corresponding pump housing. This embodiment enables system efficiencies of approximately 20%, which is substantially higher than other commercial VADs and ensures a low running temperature and enhanced blood compatibility.

Preferably in these embodiments of the present invention, the polymeric material, which is used for construction of the embodiment, may include desirable physical requirements which allow said polymeric material to be used in a safe and/or reliable manner as a blood

pump. The inclusion of polymeric components and/or material may lead to significant advantages including: improved biocompatibility, reduced energy usage and reduced production cost and time. The preferred physical requirements may include at least a limited ability to: resist permeability by fluids; be of sufficient hardness; be of sufficient fracture resistance; be of sufficient wear resistance; be of sufficient tensile and/or compressive strength. The preferred physical requirements may also include: biocompatibility, chemical stability, resistance to biodegradation and/or the ability to be sterilised without being degraded or substantially damaged.

Dimensional stability and impermeability are also preferable properties for polymers used to construct these embodiments. The preferred hydrodynamic lift design of the previous embodiment is dependent on the maintenance of dimensional stability for optimal pump function, specifically the suspended rotor functions through hydrodynamic bearings; these bearings may be integrally formed on the surface of the impeller.

Impermeability may also be highly desirable so as to prevent dimensional changes in the pump due to fluid absorption. When in use, the polymeric components may absorb fluids, blood and/or water. This absorption may distort the shape and/or the configuration of the polymeric components. In the most severe cases, this fluid absorption may impair, impede or block performance of the hydrodynamic lifts and the general functionality of the impeller in the pump. Impermeability is also preferred for protection against leaching of any metallic compounds or similar bio-toxic compounds from within the pump components or corrosion of magnets embedded within the impeller. To prevent leaching occurring between the magnets and the polymeric material of the impeller it is preferable that a non-biotoxic barrier or layer is disposed therebetween. This barrier may for instance be a metal, metallic compound or Parylene™.

Also, it is important to note that the preferred polymeric parts or components may preferably be resistant to mechanical wear. Poor wear behaviour may lead to the generation of wear particles which may then lead to various types of incompatibility with the patient's body, including thromboembolism, and may also generate a foreign body response in the tissues downstream of the pump wearing of pump.

It may also be preferable to modify these polymer materials further by surface modification so that they may better meet the desirable physical requirements for use as an implantable blood pump.

Appropriate surface modification of some polymeric materials may better address some of the aforementioned physical requirements, by creating a tough, impermeable surface layer, ensuring good dimensional stability and/or a high level of wear resistance.

Preferably, a further embodiment of the present invention includes an application of the polymer implantation process that may be applied to a complex shape. A treatment or application of ion implantation would increase wear resistance of the polymers components in the envisaged mechanical systems.

Please note that the embodiments of the present invention may also be constructed from a combination of: polymeric materials and ceramic materials; or polymeric materials and metallic materials.

Surface modification treatment may increase the rigidity, impermeability and wear resistance of the polymeric material and enable these materials to better address the major requirements to be used in the construction of implantable blood pumps that are more compatible with a patient's body and less costly to produce than previous devices.

The following three types of surface modification have been developed and may be included within further embodiments of the present invention:

1. Implantation

The modification of a preferred polymer surface may be achieved by means of ion implantation and preferably using hydrogen ions. The effect of hydrogen ion implantation has been shown to be successful in increasing the indentation hardness of polymeric material. The effect of this treatment is consistent with the formation of crosslinks in the surface layers. Since this crosslinking increases the elastic moduli, it is preferable to implant ions to promote only the optimal level of crosslinking for heart pump applications. Ion implantation methods may use hydrogen and/or heavier gas ions,

including argon, oxygen and nitrogen, as well as methane and/or other hydrocarbons acting with the surface properties of selected polymers.

Implantation may preferably be conducted by immersion of the polymer samples in a glow discharge with application of high voltage pulses of up to 20 kV from a pulse bias power supply. Since the polymers are insulators and normally charge up when ions are implanted, a method for preventing this process from limiting the implantation dose may be required. This charge effect may be prevented by using a thin metal coating, which is preferably applied by sputter deposition or physical vapour evaporation techniques.

Please note that said thin coating of metal also may be sufficient to assist the aforementioned preferred qualities of the implantation polymeric material. The coating may be thick enough to conduct sufficient charge during the time between which pulses are applied.

2. Coatings

Since carbon, including amorphous carbon and diamond-like coatings have been found to be the best performing coating material for a metal rotor and housing, the polymeric components of the embodiments may also preferably be coated with a carbon film or a thin diamond-like coating. Coatings may preferably be applied to polymers enhanced or assisted by different processes. These processes may include: magnetron sputtering, Chemical Vapour Deposition ('CVD'), Physical Vapour Evaporation Deposition ('PVD') or Parylene™ coating. A Parylene coating may preferably take the form of a coating made of the C dimer.

The Parylene dimer is created by combining two identical molecules, the key member in the family of polymers used in the Parylene conformal coating process. This dimer (diparaxylene) is heated to approximately 150°C, resulting in conversion to a gaseous monomer. Coating thicknesses and uniformity are both controlled by the amount and the purity of the dimer used. Parylene C is optically clear and is inert and insoluble in most solvent systems within its useful range of temperatures. Parylene C may be used to 125°C continuously in the presence of oxygen.

3. Combined implantation and coating

Preferably, the pre-treatment of the polymer with gas ions as in the aforementioned ion treatment may be used in conjunction with a deposition phase as of the aforementioned coating. The optimal performance using this type of combined processing will minimise the tendency of the softer substrate to yield underneath a harder coating when under impact conditions and will match the hardening effect achieved by gas ion implantation with the hardness of the coating.

Further preferred embodiments may have particular, although not exclusive, application for implantation within a mammalian body so as to at least assist the functioning of the heart. In practice, this is preferably performed by placing the pump assembly entirely within the body of the mammal and connecting the pump between the left ventricle and the aorta so as to assist left side heart function. It may also be connected to the right ventricle and pulmonary artery to assist the right side of the heart.

The preferred pump assembly may include an impeller which is fully sealed within the pump body or housing. This configuration may not require a shaft extending through the pump body to support it. The impeller may be partially or fully suspended, in use, within the pump body by the operation of hydrodynamic forces imparted as a result of the interaction between the rotating impeller, the internal pump walls and the fluid, which the impeller causes to be urged from an inlet of the pump assembly to an outlet thereof.

It is also important to note that a device constructed substantially of polymeric components may be less susceptible to electrical eddy currents generated by the electric motor. Traditionally, in a metallic blood pump, the pump is usually driven by a magnetic driving force, this driving force of the motor induces electrical eddy currents within the metallic housing and/or impeller. These eddy currents may result in substantial current losses and gross efficiencies within the design of the blood pump and may impede overall pumping performance.

A third embodiment of the present invention is the centrifugal pump 27, as depicted in figure 3, if for use with human patients to pump bodily fluids, preferably blood. The pump housing 31, can be fabricated in two parts, a front part 32 in the form of a housing body and a back part 34 in the form of a housing cover, with a smooth join therebetween,

for example at 33 in figure 3. The pump 27 has an axial inlet 43 and a tangential outlet. The rotating part or impeller 37 is of simple form, comprising only blades 30 and a blade support 29 to hold those blades fixed relative to each other. The blades may be curved or straight, in which case they can be either radial or tilted, i.e., at an angle. This rotating part 37 will hereafter be called the impeller 37, but it also serves as a bearing component and as the impeller of a motor configuration as to be further described below whereby a torque is applied by an electromagnetic means to the impeller 37. Note that the impeller has no shaft and that fluid enters the region of its axis 43. Some of the fluid passes in front of the support cone 28 and some behind it, so that the pump 27 can be considered of two-sided open type, as compared to conventional open centrifugal pumps, which are only open on the front side. Approximate dimensions found adequate for the pump 27 to perform as a ventricular assist device, when operating at speeds 2000 - 4000 rpm, are outer blade diameter of 40 mm, outer housing average diameter 60mm, and housing axial length 40mm.

As the blades 30 move within the housing, some of the fluid passes through the gaps, much exaggerated in figure 3, between the blade edges and the housing front face 29 and the housing back face 36. Generally, in open centrifugal pumps, the gaps are made small because this leakage flow lowers the pump hydrodynamic efficiency. In the pump disclosed in this embodiment, the gaps are made slightly smaller than is conventional in order that the leakage flow can be utilised to create a hydrodynamic bearing. For the hydrodynamic forces to be sufficient, the blades may be tapered, so that the gap between the blade and the housing is larger at the leading edge of a blade than at the respective trailing edge of the blade. Preferably, a fluid that passes through the gap thus experiences a wedge shaped restriction, which generates a thrust force, as described in Reynolds' Theory of Lubrication. This thrust force is proportional to the square of the thickness of the blade at the edge, and thus thick blades are favoured, since if the proportion of the pump cavity filled by blades is constant, then the net thrust force will be inversely proportional to the number of blades.

For manufacturing simplicity, the housing front face 29 can be conical, with an angle of around 45^0 so that it provides both axial and radial hydrodynamic forces. Other angles

are suitable that achieve the functional requirements of this pump including the requirements for both axial and radial hydrodynamic forces.

Other curved surfaces are possible provided both axial and radial hydrodynamic forces can be produced as a result of rotation of the blades relative to the housing surfaces.

In this preferred embodiment, for manufacturing simplicity and for uniformity in the flow axial direction 43, the housing back face 36 is made flat over the bearing surfaces, i.e. under the blade edges. With this the case, a slacker tolerance on the alignment between the axes of the front part 32 and back part 34 of the housing 31 is permissible. An alternative is to make the back face 37 conical at the bearing surfaces with taper in the opposite direction to the front face 29, so that the hydrodynamic forces from the back face will also have radial components. Tighter tolerance on the axes alignment may then be required, and some of the flow would have to undergo a reversal in its axial direction. There may be some advantage in making the housing surfaces and blade edges non-straight, with varying tangent angle, although this will impose greater manufacturing complexity.

There are several options for the shape of the taper, but in the preferred embodiment, the amount of material removed simply varies linearly or approximately linearly across the blade. For the back face, the resulting blade edges are then planes at a slight inclination to the back face. For the front face, the initial blade edges are curved and the taper only removes a relatively small amount of material so they still appear curved. Alternative taper shapes can include a step in the blade edge, though the corner in that step would represent a stagnation line posing a thrombosis risk.

For a given minimum gap, at the trailing blade edge, the hydrodynamic force is maximal if the gap at the leading edge is approximately double that at the trailing edge. Thus the taper, which equals the leading edge gap minus the trailing edge gap, should be chosen to match a nominal minimum gap, once the impeller has shifted towards that edge. Dimensions which have been found to give adequate thrust forces are a taper of around 0.05 mm for a nominal minimum gap of around 0.05 mm, and an average circumferential blade edge thickness of around 5 mm for 4 blades. For the front face, the taper is measured within the plane perpendicular to the axis. The axial length of the housing

between the front and back faces at any position should then be made about 0.2 mm greater than the axial length of the blade, when it is coaxial with the housing, so that the minimum gaps are both about 0.1 mm axially when the impeller 37 is centrally positioned within the housing 31. Then, for example, if the impeller shifts axially by 0.05 mm, the minimum gaps will be 0.05mm at one face and 0.15 mm at the other face. The thrust increases with decreasing gap and would be much larger from the 0.05 mm gap than from the 0.15 mm gap, about 14 times larger for the above dimensions. Thus there is a net restoring force away from the smaller gap.

Similarly, for radial shifts of the impeller the radial component of the thrust from the smaller gap on the conical housing front face would offer the required restoring radial force. The axial component of that force and its torque on the impeller would have to be balanced by an axial force and torque from the housing back face, and so the impeller will also have to shift axially and tilt its axis to be no longer parallel with the housing axis. Thus as the person moves and the pump is accelerated by external forces, the impeller will continually shift its position and alignment, varying the gaps in such a way that the total force and torque on the impeller 37 match that demanded by inertia. The gaps are so small, however that the variation in hydrodynamic efficiency will be small, and the pumping action of the blades will be approximately the same as when the impeller is centrally located.

While smaller gaps imply greater hydrodynamic efficiency and greater bearing thrust forces, smaller gaps also demand tighter manufacturing tolerances, increase frictional drag on the impeller, and impose greater shear stress an the fluid. Taking these points in turn, for the above 0.05 mm tapers and gaps, tolerances of around ± 0.015 mm are needed which imposes some cost penalty but is achievable. A tighter tolerance is difficult, especially if the housing is made of a plastic; given the changes in dimension caused by temperature and possible absorption of fluid by plastic. The frictional drag for the above gaps produces much smaller torque than the typical motor torque. Finally, to estimate the shear stress, consider a rotation speed of 3000 rpm and a typical radius of 15 mm, at which the blade speed is 4.7 ms^{-1} and the average velocity shear for an average gap of 0.075 mm is $6.2 \times 10^{4} s^{-1}$. For blood of dynamic viscosity 3.5×10^{-3} $kgm^{-1}s^{-1}$, the average shear stress would be 220 Nm^{-2}. Other prototype centrifugal blood pumps with closed

blades have found that slightly larger gaps, e.g. 0.15 mm, are acceptable for haemolysis. A major advantage of the open blades of the present invention is that a fluid element that does pass through a blade edge gap will have a very short residence time in that gap, around $2x10^{-3}$ s. and the fluid element will most likely be swept through the pump without passing another blade edge.

To minimise the net force required of the hydrodynamic bearings, the net axial and radial hydrodynamic forces on the impeller from the bulk fluid flow should be minimised, where "bulk" here means other than from the bearing thrust surfaces.

One method of minimising the bulk radial hydrodynamic force is to use straight radial blades has virtually no radial component. The radial force on the impeller depends critically on the shape of the output flow collector or volute 35. The shape should be designed to minimise the radial impeller force over the desired range of pump speeds without excessively lowering the pump efficiency. The optimal shape will have a roughly helical perimeter between the "cut water" and outlet. The radial force can also be reduced by the introduction of an internal division in the volute 35 to create a second output flow collector passage, with tongue approximately diametrically opposite to the tongue of the first passage.

In regard to the bulk axial hydrodynamic axial force, if the blade cross-section is made uniform in the axial direction along the relational axis, apart from the conical front edge, then the pressure acting on the blade surface (excluding the bearing edges) will have no axial component. This also simplifies the blade manufacture. The blade support cone 9 must then be shaped to minimise disturbance to the flow over the range of speed, while maintaining sufficient strength to prevent relative blade movement. The key design parameter affecting the axial force is the angle of the cone. The cone is drawn in figure 3 as having the same internal diameter as the blades, which may aid manufacture. However, the cone could be made with larger or smaller internal diameter to the blades. There may be an advantage in using a non-axisymmetric support "cone", e.g. with a larger radius on the trailing surface of a blade than the radius at the leading surface of the next blade. If the blades are made with non-uniform cross-section to increase hydrodynamic efficiency, then any bulk hydrodynamic axial force on them can be

balanced by shaping the support cone to produce an opposite bulk hydrodynamic axial force on it.

Careful design of the entire pump, employing computational fluid dynamics, is necessary to determine the optimal shapes of the blades 30, the volute 35, the support cone 28 and the housing 32, in order to maximise hydrodynamic efficiency while keeping the bulk fluid hydrodynamic forces, shear and residence times low. All edges and the joins between the blades and the support cone should be smoothed.

The means of providing the driving torque on the impeller 37 of the preferred embodiment of the invention is to encapsulate permanent magnets in the blades 30 of the impeller 37 and to drive them with a rotating magnetic field pattern from oscillating currents in the windings 39 and 40, fixed relative to the housing 31. Magnets of high remanence such as sintered rare-earth magnets should be used to maximise motor efficiency. The magnets should be aligned axially or approximately axially, with alternating polarity for adjacent blades. Preferably, the preferred embodiment may include four blades but other embodiments of the present invention may also function in a similar manner and these embodiments may include other amounts of blades within the impeller design.

There are many options for locating the magnets within the blades 30. The most preferred is for the blade to be made of magnet material apart from a biocompatible shell or coating to prevent fluid corroding magnets and to prevent magnet material (which may be toxic) entering the blood stream. The coatings should be sufficiently durable especially at blade corners to withstand rubbing during start-up or during inadvertent bearing touch down.

Finally, to create the alternating blade polarity the impeller must be placed in a special pulse magnetisation fixture, with an individual coil surrounding each blade. The support cone may acquire some magnetism near the blades, with negligible influence.

All edges in the pump should be radiused and surfaces smoothed to avoid possible damage to formed elements of the blood.

The windings 39 and 40 of the preferred embodiment are slotless or air-gap windings, following the blade curvature, with the same pole number as the impeller, namely four poles in the preferred embodiment. A ferromagnetic iron yoke 41 of conical form for the front winding and an iron ferromagnetic yoke 42 of annular form for the back winding may be placed on the outside of the windings to increase the magnetic flux densities and hence increase motor efficiency. The winding thicknesses should be designed for maximum motor efficiency, with the sum of their actual thicknesses somewhat less than but comparable to the magnet axial length. The yokes can be made of solid ferromagnetic material such as iron. To reduce "iron" losses, the yokes 41 can be laminated, for example by helically windings thin strip, or can be made of iron/powder epoxy composite. Alternatively they can be helically wound to reduce iron losses. The yokes should be positioned such that there is zero net axial magnetic force on the impeller when it is positioned such that there is zero net axial magnetic force on the impeller when it is positioned centrally in the housing. The magnetic force is unstable and increases linearly with axial displacement of the impeller away from the central position, with the gradient being called the positive stiffness of the magnetic force. This unstable magnetic force must be countered by the hydrodynamic bearings, and so the stiffness should be made as small as possible. Choosing the yoke thickness such that the flux density is at the saturation level reduces the stiffness and gives minimum mass. An alternative would be to have no iron yokes, completely eliminating the unstable axial magnetic force, but the efficiency of such designs would be lower and the magnetic flux density in the immediate vicinity of the pump may violate safety standards and produce some tissue heating. In any case, the stiffness is acceptably small for slotless windings with the yokes present. Another alternative would be to insert the windings in slots in laminated iron stators which would increase motor efficiency and enable use of less magnet material and potentially lighter impeller blades. However the unstable magnetic forces would be significant for such slotted motors. Also, the necessity for fat blades to generate the required bearing forces allows room for large magnets, and so slotless windings are chosen in the preferred embodiment.

The winding connection of the preferred embodiment is for three wires, one wire per phase, to connect a sensorless electronic controller to winding 39.

In the preferred embodiment, the two housing components 32 and 34 are made by injection moulding from non conducting plastic materials. The windings and yokes are encapsulated within the housing during fabrication moulding. In this way, the separation between the winding and the magnets is minimised increasing the motor efficiency and the housing is thick, increasing its mechanical stiffness. Alternatively, the windings can be positioned outside the housing and the thickness of these windings is preferably at least 2 mm for sufficient stiffness.

If the housing plastic is hygroscopic or if the windings are outside the housing, it may be necessary to first enclose the windings and yoke in a very thin impermeable shell. Ideally, the shell should be non-conducting (such as polymers).

By keeping the windings separate for the front and back faces, the windings can be moulded into the front and back housing parts. Alternatively, for the case of windings not moulded into the housing, it may be possible to wind the coils onto the assembled housing, passing the coils from the front face to the back face over the volute 35.

The combining of the motor and bearing components into the impeller in the preferred embodiment provides several key advantages. The rotor consequently has very simple form, with the only cost of the bearing being tight manufacturing tolerances. The rotor mass is very low, minimising the bearing force needed to overcome weight. Also with the bearings and the motor in the same region of the rotor, the bearings forces are smaller than if they had to provide a torque to support magnets at an extremity of the rotor.

A disadvantage of the combination of functions in the impeller is that its design is a coupled problem. The optimisation should ideally link the fluid dynamics, magnetics and bearing thrust calculations. In reality, the blade thickness can first roughly sized to give adequate motor efficiency and sufficient bearing forces with a safety margin. Both requirements are met for four blades of approximate average circumferential thickness 5mm. The housing, blade and support cone shapes can then be designed using computational fluid dynamics, maintaining the above minimum average blade thickness. Finally the motor stator, i.e. winding and yoke, can be optimised for maximise motor efficiency.

In another preferred embodiment, the blood pump may include a rotor or impeller constructed of polymeric materials wherein said polymeric material is capable of incorporating magnetic characteristics. Additionally, these magnetic characteristics may be used to apply a driving or an urging force to rotate the impeller or rotor.

The main magnetic characteristics of the polymeric material may result from construction of different types of magnetic plastics. Generally, the construction of magnetic plastic is achieved by the use of a magnetic type filler within the plastic material. The following list is presented as indicative of certain magnetic plastics, commercially available, and is not a comprehensive list.

Type of a filler	Magnetic energy, kJ/m	Residual induction, T	Coercive force, kA/m
Barium ferrite	11.0	0.29	185.0
Samarium- cobalt	38.7	0.48	540.0
Neodymium-iron-boron	100.0	0.64	700.0

The top limit of operating range of temperature of these types of magnetic plastics (without deterioration of service properties) is approximately 100° – 150°C. It is also important to note that this temperature stability of magnetic plastics is significantly greater than temperature stability of permanent magnets produced with traditional methods.

Use of magnetic plastics in production of multi-pole magnetic systems of rotors of thyratron motors is especially effective. This motor have several distinctive features: high magnetic induction on the surface of poles, high electrical resistance at work in alternating magnetic fields, small dimensions, high mechanical strength, lower labour

input of manufacture, in comparison with other existing systems. Motors constructed of magnetic plastics with more than 2 poles and an overall size of less than 20mm are capable of speeds between 350-7500 rpm.

The stators of any of the above embodiments may be constructed of a material that is capable of generating a magnetic field when a electrically current is applied.

In a further embodiment of the present invention, it is also envisaged that a blood device may be constructed of polymeric compound such as in the above described embodiments but the outer surface of the polymeric components may be coated with a metal.

Preferably, this metal may coat the regions of the pump that are in direct contact with a patient's blood supply or in regions of increased wear.

In another preferred embodiment of the present invention, the pump device may include a casing and housing which are integrally formed in a one-piece construction. This one piece construction may be of benefit as it would allow the device to be manufactured by injection moulding or constructed in a simply process.

This embodiment is shown in figure 4. This embodiment may be constructed by positioning and suspending an impeller 60 in solution, which is capable being solid at room temperature and in a liquid state when temperature is increased. The impeller 60 may inserted into the solution at higher than room temperature and when the solution cools it sets solid with the impeller 60 suspended within it.

The solid solution may then be shaped and serve as an inner mould for the forming the polymer blood pump 62. The solid solution may preferable be in the shape of the air space 63.

The stators 61 & 58 and other assorted electric components may then be positioned in a mould respectively above and below the solid solution. Then polymer may fill the mould around the solid solution to form the casing and housing of the pump device. This polymer may preferably include thermo-set plastic which is not easily meltable after being set. Additionally, the solid solution will need to stay in a solid state whilst the casing 59 is being formed, this can be achieved by quickly setting the polymer or by using

a solid solution with higher melting point. The pump is then warmed to a temperature suitable to melt the solid solution and then this solution will evacuate the space cavity, leaving impeller 60 within the cavity.

Preferably, the solid solution may be wax or a substance exhibiting similar properties, which can liquefy at low temperatures.

The result of this moulding process may be a blood pump device 62 which includes a one-piece casing and shroud arrangement 57 and an impeller 60 is centred within an air space 57.

Alternately, the solid solution in space 57 may be replaced with a stylised and specially shaped and sealed bag containing a biocompatible liquid and an impeller 60. This stylised bag preferably is in the shape of cavity 57. This bag may be used to mould the inner surface of the pump cavity 57 instead of using the solid solution. Once moulding of the casing 59 has taken place, this bag may be burst, deflated and removed from the cavity. This technique is similar to paper máche moulding.

Alternately, the pump casing and shroud 59 of the embodiment, shown in figure 4, may be constructed using stereo-lithography ("SLA") techniques and/or selective laser centering ("SLC"). Please note that some preferred embodiment of the present invention may be constructed by injection moulding.

In a further embodiment of the present invention it may be possible to incorporate a polymer which is impregnated or coated with a pharmaceutical product and this polymer may be biodegradable. This polymer also may, in vivo, present a bioactive agent on its surface and/ or slowly release a pharmaceutical product into the patient's circulatory system. By way of example, pharmacologically active agents presented to the blood on the polymer surface or released into bloodstream by the polymer may include: Heparin™, anti-clotting agent, and anti-microbial agents. It is envisaged that this arrangement may facilitate long term pharmacological surface interactions with the blood and/or the slow release or eluting of drugs or pharmaceuticlogical agents into the patient's system, including antimicrobial agents for infection resistance.

Alternately in another embodiment of the present invention, the casing and housing may be constructed of a silicone polymer.

Preferably, a further embodiment of the present invention may include an impeller. Two different versions of preferred impellers are shown in figures 5 & 6.

These impellers preferably include at least two blades, but it is noted that in figures 5 & 6 four blades are shown. Four blades preferably give stability to the impeller configuration.

In figure 5, the blades 45 of the impeller 46 are generally fin shaped and in figure 6 the blades 48 of the impeller 50 are generally tear-shaped. These two embodiments of the impeller represent the most preferred configurations for an impeller that is constructed at least partially from polymeric components. In figure 5, the blades are joined by supports 47 which are preferred to be arranged so as to provide no net thrust force. In figure 6, similar support, 49 operate in a similar manner to those in the embodiment shown in figure 5.

In figure 7, an impeller 55 is depicted as including four blades 54. Each of these blades 54 are supported in position by two groups of generally parallel supports 52 and 53. These supports may be modified at the point of joining to the respective blades to allow channels 51 to be formed.

Each channel may allow increased fluid performance and also allow for pressure differentials created by the tapered angle of the blades. The two groups of supports 52 and 53 may also increase the dimension stability of the impeller 55 and may also increase impeller stiffness which may be desirable.

It is important to note other preferred embodiments of the present invention may be constructed of any polymers that display the following features: resistance to permeability of fluids and water; dimensional stability; high degree of stiffness; mechanical stability; biocompatibility and/or haemocompatibility; and general biochemical inertness.

The polymeric material must be resistant to permeable by bodily fluid and/or water, or may have a low and predictable uptake such liquids with no deleterious effects.

The polymeric material may also need be dimensionally stable and thereby be generally resistant to changes in shape and size after manufacture. This may be affected by the degree of crystallinity (more crystallisable polymers generally shrink more upon freezing than amorphous polymers) as well as the presence of fibres which will reduce shrinkage (but might introduce orientation during moulding).

Another desired physical characteristic of the polymeric material may be includes sufficient stiffness. Typically, most stiff polymers have low breaking strains and so their toughness is low. This may also be exacerbated by the presence of glass fibres, even in otherwise ductile polymer matrices. For applications of relating to blood pumps, toughness may be of less importance than dimensional stability or biochemical inertness.

It may also necessary to use a polymeric material which possess a consistent or at least predictable modulus with time. Un-reinforced polymers show substantial viscoelastic behaviour at or near the softening temperature. For this to be small, it may be necessary for the polymer to have at least one of the following properties to some degree: a high degree of crystallinity so that any viscous behaviour is associated with a small fraction of the solid matter (i.e. the amorphous content); a softening temperature (or glass transition temperature ('Tg')) well above the service temperature. In respect of applications to a blood pump the service temperature is generally 37°C, so the glass transition preferably may be well above 100°C to minimise both changes in modulus in time, as well as make the product dimensionally stable; and fibre reinforcement (if reinforcement is necessary) arranged to discourage viscous flow as this will ensure retention of stiffness and strength at elevated temperatures, but may reduce breaking strain.

A polymeric material to be used in the construction of an embodiment may also include to some degree biocompatibility and/or haemocompatibility.

Additionally a polymeric material may be used in the construction of an embodiment may also include to some degree a level of biochemical inertness. Many polymers of high molecular weight are insoluble and are quite inert. However long molecular weight polymers such as condensation polymers including polyamides and certain polyurethanes can either possess smaller (oligomeric) fractions or be susceptible to hydrolytic attack. Therefore toxic fragments may form and cause adverse interactions.

Additionally, please note that figures 1, 2, 3 & 4 of the accompanying drawings show potential applications or embodiments relating to third generation left ventricle assist devices ('LVADs'). The present invention may also include embodiments relating to applications with first, second, third or future subsequent generations of blood pumps.

First generation blood pumps are generally pumps that generate a pulsatile blood flow through using a bellows type pumping motion. First generation blood pump designs are typically reliant on valves and as such these pumps generally include many points of blood stagnation and/or sites for thrombogenesis.

Second generation blood pumps are generally centrifugal or rotary blood pumps that include a mechanical bearing to mount an impeller within a housing. Typically, these mechanical bearings comprise a pivot bearing connected to a shafted impeller. The shafts and the pivot bearings both, in use, become sites for the formation of blood clots.

Third generation blood pumps generally comprise a rotary blood pump with a magnetic, hydrodynamic and/or buoyancy bearing systems. These third generation pumps typically have fewer points for stagnation in the blood path are therefore the generally preferred design of implantable blood pumps.

Figure 8 shows a cross sectional view of an impeller blade 60. Generally, this impeller blade 60 may be a blade of the impellers shown in figure 5, 6 or 7. The blade 60 is made or constructed of a preferred polymeric material 57. Embedded within the centre of impeller 60 is permanent magnet 58 and this magnet 58 is surrounded by the polymeric material 57. As permanent magnets generally comprise bio-toxic compounds, it is necessary to insulate the bio-toxic material from the blood flowing past the blade 60, when in use. Additionally, it is important to note that most polymeric materials are at least partially susceptible to fluid permeation and as such bio-toxic compounds may degrade and release toxic chemicals or compounds in a patient's circulatory system.

Hence it may be preferable to coat pump components in an impermeable barrier or layer to block, stop or greatly impede the eluting or release of bio-toxic compounds or chemicals into the patient's blood stream. In figure 8, barrier 59 encases, coats or seals the permanent magnet 58. Barrier 56 encases, coats or seals the polymeric material layer 57.

Preferably, these barriers 56 & 59 may be constructed from a non-biotoxic material such as metal, metallic compound or Parylene™ or a similar impermeable coating material.

The following polymeric substances are examples of materials from which an embodiment may be constructed.

Polyetheretherketone ('PEEK')

An example of a polymeric material that may be used in the constructions of an embodiment is PEEK. It has a relatively high thermal stability compared with other thermoplastics. It typically retains high strength at elevated temperatures, and has excellent chemical resistance (being essentially inert to organics, and has a high degree of acid and alkali resistance). It has excellent hydrolytic stability and gamma radiation resistance. Therefore PEEK may be readily sterilised by different routes. It also shows good resistance to environmental stress cracking. It generally has excellent wear and abrasion resistance and a low coefficient of friction. PEEK may incorporate glass and/or carbon fibre reinforcements which may enhance the mechanical and/or thermal properties of the PEEK material.

PEEK may be easily processed on conventional extrusion and injection moulding equipment. Post-annealing and other processes obvious to a person skilled in the art may be preferable. A polyaromatic, semicrystalline polymer may also be used in construction of an embodiment.

Other examples of this polymer include: Polyaryletherketone ('PAEK') manufactured by Vicktrex and PEEK-OPTIMA LT™ which is a polymer grade with properties optimised for long-term implants. PEEK-OPTIMA LT™ is significantly stronger than traditional plastics currently available. Generally, PEEK may be able to withstand more aggressive environments and maintain impact properties over a broader range of temperatures than other polymers.

It has been shown that carbon fibre reinforced PEEK found to exhibit excellent resistance to a saline environment at 37°C designed to simulate human body conditions.

PEEK includes the significant advantage of generally supplying dimensional stability, when in use.

Fibre reinforced polymer ('FRP')

Another example of an polymeric material that may be included within an embodiment of the present invention is FRP. FRPs are constructed of composites of PEEK and other polymers. PEEK may be reinforced with 30% short carbon fibres and which when subjected to saline soaking, was found to exhibit no degradation in mechanical properties. In contrast, a 30% short carbon fibre reinforced polysulphone composite has been found to show degraded mechanical properties due to the same saline soaking.

The fibre /matrix bond strength may significantly influence the mechanical behaviour of FRP composites. Interfacial bond strength durability is therefore particularly important in the development of FRP composites for implant applications, where diffused moisture may potentially weaken the material over time. Testing in physiologic saline at 37°C showed that interfacial bond strengths in carbon fibre/polysulfone and carbon fibre/polyetheretherketone composites significantly decrease.

It should be noted that the fibre/matrix bond strength is known to strongly influence fracture behaviour of FRP composites.

Polycarbonate ('PC')

Another example of polymer material that may be used in the construction of a preferred embodiment are PC resins. PC resins are widely used where transparency and general toughness are sought.

PC resins are intrinsically amorphous due to the large bulky bis-phenol component. This means that the polymer has a significantly high free volume and coupled with the polar nature of the carbonate group, the polymer can be affected by organic liquids and by water. PC resins are not as resistant to extremes in pH as PEEK however they are at least partially resistant.

PC resins generally have very low levels of residual monomers and so PC resins may be suitable for blood pump construction. PC resins generally have desirable mechanical and

thermal properties, hydrophobicity and good oxidative stability. PC resins are desirably used where high impact strength is an advantage. PC resins also generally confer good dimensional stability, reasonable rigidity and significant toughness, at temperatures less than 140°C.

PC resins may be processed by all thermoplastic processing methods. The most frequently used process is injection moulding. Please note that it may be necessary to keep all materials scrupulously dry due to small but not negligible moisture pick-up of this resin. The melt viscosity of the resin is very high, and so processing equipment should be rugged. Processing temps of PC resins are relatively high generally being between approximately 230°C and 300°C.

Polysulphone ('PS')

Another example of a polymeric material that may be used to construct parts of an embodiment from is PS. PS has relatively good high temperature resistance, and rigidity. PC is generally tough but not notch-sensitive and is capable of use up to 140°C. It has excellent hydrolytic stability and is able to retain mechanical properties in hot and wet environments. PS is generally chemically inert.

PS is similar to PC resins but may be able to withstand more rigorous conditions of use. Additionally, PS is generally more heat resistant, and possesses a greater resistance to creep and better hydrolytic stability. PC has a high thermal stability generally due to bulky chemical side groups and rigid chemical main backbone chains. It is also generally resistant to most chemicals.

Injection moulding used for lower melt index grades, whilst extrusion and blow moulding is used to form components generally made of higher molecular weight PS.

Polyurethanes (PU)

Another example of a polymeric material that may be include within an embodiment of the present invention is PU. PU is one of the most biocompatible and haemocompatible polymeric materials. PU has the following properties: elastomeric characteristics; fatigue resistance; compliance and acceptance or tolerance in the body during healing; propensity

for bulk and surface modification via hydrophilic/hydrophobic balance or by attachments of biologically active species such as anticoagulants or bio-recognisable groups. Bio-modification of PU may be possible through the use of a several antioxidants used in isolation or in combination. These antioxidants may include vitamin E, which may create materials which can endure in a patient's body for several years.

PU constitutes one of the few classes of polymers that include the properties of being generally highly elastomeric and biocompatible.

Polyether Polyurethanes ('PEPU')

Another polymeric material that may be used in the construction of an embodiment is PEPU. PEPU generally has: relatively good flexural performance, acceptable blood compatibility, and is relatively easy to processing. However unmodified PEPU may degrade and may also be readily permeable to water, which is not typically desirable.

Polycarbonate Urethane ('PCU')

PCU may also provide another alternative polymeric material for the purpose of constructing an embodiment. PCU has significantly lower rates of water transmission or impermeability. This is due to inherently lower chain mobility of the carbonate structure in the soft segment phase. Additional impermeability to water vapour can be achieved by selecting a polyurethane polymer with high hard segment content, and aromatic rather than aliphatic di-isocyanate co-monomer, and a more hydrophobic surface.

PCU generally has oxidative stability of the carbonate linkage, which reduces the rate of biodegradation tremendously as compared to the polyether polyurethanes.

PCU results of blood compatibility testing of polyether polyurethanes in comparison with polycarbonate polyurethanes.

Siloxane-Urethanes ('SiU')

SiU is another example of an alternative preferred polymeric material. SiU generally has a combination of properties including: fatigue strength, toughness, flexibility and low interaction with plasma proteins. However these polymers may be relatively soft.

Polyvinylchloride ('PVC')

PVC is another example of an alternative preferred polymeric material. PVC is a relatively amorphous and rigid polymer which in the absence of plasticiser has a glass transition around Tg 75°C -105°C. It is a cheap tough polymer which is extensively used with many types of filler and other additives. Although it has a high melt viscosity and therefore in theory is difficult to process, specialised methods have been established for several decades to compound this polymer efficiently.

Extraction-resistant grades of PVC are required for long-term blood compatibility. Plasticised PVC has been well established for blood bags and similar devices, and resin manufacturers can keep toxic residual monomer levels acceptably low (<1ppm). However there is enormous social pressure to outlaw PVC despite scientific data which generally indicates that PVC is benign.

Please note that the use of toxic metal stabilisers generally common in manufacture of PVC are preferably not to be use for implantation applications.

Poly vinylidene fluoride ('PVDF')

PVDF is a polymer that possesses relatively good amounts of toughness and biocompatibility to be suitable for use in constructing an embodiment.

Polyethylene ('PE')

PE is available in several major grades, including Low Density PE ('LDPE'), High Density PE ('HDPE') and Ultra High Molecular Weight Grade PE ('UHMWPE'). However the UHMWPE may be likely to be the most suitable as it generally possesses relative toughness, low moisture absorption, and good overall chemical resistance.

Highly oriented grades are used for needle stick resistant gloves and in several other high modulus applications such as fencing garments. However these commercial high modulus fibres have rather poor creep and thermal performance. Fibres have also been employed by Ray as containment in association with other hydrophilic polymers, as synthetic nucleus disks for spinal implant procedures.

Sintered and compression moulded UHMWPE has been well established for hip joints replacement. However further improvements appear necessary, as abrasive resistance and wear are not suitable for lengthy (>5-10 year) use. A major limitation of PE is thermal performance (melting point approximately 130°C) and dimensional stability.

Polypropylene ('PP')

Another suitable polymeric material is PP. PP is a versatile polymer that may possess a combination of features including: relative inertness, relatively good strength and good thermal performance. Depending on the grade, Tg ranges from 0°C to -20°C and the MPt is approximately 170°C. The most common grades are homo- and ethylene copolymers, the latter with improved toughness.

In addition, there have been many advances in reactor technology leading to grades which are either much softer than normal or much stiffer. For example, the Bassell Adstiff™ polymers made using Catalloy™ technology may be suitable and/or include desirable features for use in the manufacture of a blood pump. Generally, PP polymers lack the high melting point of PEEK, but this property is not generally desired.

Polymethylmethacrylate (PMMA)

PMMA is an amorphous material with good resistance to dilute alkalis and other inorganic solutions, and has been shown to be one of the most biocompatible polymers. Therefore, PMMA may include some of the desirable features and may be used in the construction of an embodiment of the present invention. Generally, PMMA easily machined with conventional tools, moulded, surface coated and plasma etched.

PMMA's may be susceptible to environmental stress cracking although this is usually associated with the use of organic solvents, not present in a patient's body and a blood pump working environment.

Acrylonitrile-Butadiene-Styrene Terpolymers (ABS)

ABS generally have relatively good surface properties including: hardness, good dimensional stability and reasonable heat resistance (Tg approximately 120°C). The

combination of the three monomers imparts stiffness (styrene), toughness (butadiene) and chemical resistance (acrylonitrile).

Other attributes of ABS may include: rigidity, high tensile strength and excellent toughness as well as excellent dimensional accuracy in moulding. ABS is generally unaffected by water, inorganic solvents, alkalies; acids; and alcohols. However certain hydrocarbon solvents, not usually present within the body of a patient or in the working environment of the blood pump, may cause softening and swelling on prolonged contact.

Polyesters ('PET')

PET have become one of the largest growing thermoplastics over the past decade: volumes and prices are now approaching PE and PP. PET has a Tg around 75°C and melting point of 275°C. It can vary from about 25% to 70% in crystallinity depending on the processing history of the polymer. Physical properties and chemical resistance are very dependant on crystallinity. PET may also have limited dimensional stability, as crystallisation can slowly increase after moulding. PET are generally tough, transparent, stiff and opaque.

Another class of PET with a Tg above 100°C is currently available, this polymer is called Polyethylene Naphthenate ('PEN'). PET has a degree of polarity and so has associated water uptake. PET and PEN may both be suitable for use in the construction of a blood pump.

Polyamides and/or Nylons ('PA')

PAs and Nylons are characterised by having excellent wear/frictional properties, high tensile impact and flexural strength and stiffness, good toughness and high melting points.

There are three types of polyamides which may reduce the limitations list above. Fully aromatic polyamides including Kevlar™ (*para* position) and Nomex™ (*meta* position) are commercially available and have high stiffness and melting points. Semi-aromatic polyamides are made in Germany (eg Trogamid™ T) and France. These semi-aromatic polyamides generally have good transparency and chemical resistance.

Some PAs may include relatively large hydrocarbon spacers between the amide groups. Examples of this type of PA include Nylon 11 and 12 which are generally more hydrophobic (water uptake <1%) than regular varieties of PAs. However the larger spacing leads to a loss in stiffness compared to the other polymers and thermal performance may also be compromised.

Acetal Resins and/or Polyoxymethylene ('AR')

AR may be used to construct any one of the preferred embodiments. This class of polymer is strong, hard, and abrasion resistant. It has been evaluated for joint replacement components and other long-term implants.

The acetal homo-polymer is prone to salt induced cracking, but copolymers with small amounts of a propylene oxide are possible. AR which contains formaldehyde may be of concern due to possible toxicity of formaldehyde.

Polydimethylsiloxane ('PDSM')

PDSM may be used to construct any one of the preferred embodiments. This polymer is generally elastomeric. It may also be considered for use as either a biocompatible coating or a copolymer.

Copolymers based on PDMS and PU have been developed and PDMS/PC is commercially offered by General Electric as Lexan™ 3200. The latter is a fairly stiff transparent material with excellent UV performance.

Syndiotactic Polystyrene ('SP')

SP may be used to construct any one of the preferred embodiments. SP is typically highly crystalline, little change in modulus occurs at the Tg of 100°C, and retention of properties is fairly high to the melting point of over 250°C. Many grades may be fibre reinforced, to further reduce the change in modulus at the Tg. Being a hydrocarbon with no hetero atoms, the polymer may be hydrophobic and inert.

Aliphatic ether ketones ('AEK')

AEK may be used to construct any one of the preferred embodiments. Processing and mechanical performance are similar, but this polymer shows improved high temperature aging behaviour and little notch sensitivity. Unfortunately the material lacked distinctiveness and is no longer produced.

TOPAS™ ('T')

T may be used to construct any one of the preferred embodiments. This class of co-polymer is made by Ticona in Germany. It generally comprises ethylene and norbornadene, with the Tg being controlled by monomer ratio. It is a hydrocarbon alternative to polycarbonate, and is generally suitable for medical fittings and devices. Its Tg is over approximately 130°C and It is generally transparent with the co-monomer inhibiting crystallisation of the ethylene segments.

Metallocene PP ('MPP')

MPP may be used to construct any one of the preferred embodiments. This polymer is manufactured by Exxon to compete with existing PP. It has a much narrower molecular weight distribution (polydispersity around 2) because it is oligomer-free.

Ion Implantation

Figures 9, 10, 11, 12, 13, 14 & 15 depict methods and devices to implant ions into a polymeric component, wherein said polymeric component is treated through plasma immersion ion implantation and or plasma deposition to modify and/or coat the outer surface of the polymeric components or a region close to the outer surface. This ion implantation may generally extend up to an approximate depth of 1 micrometer into said outer surface.

Preferably, the polymeric component, to be treated, may be immersed in gas plasma, which may be created by an RF antenna placed in a background of the desired gas and high voltage pulses will be applied using a pulsed power supply. Alternatively, the pulsed power supply may be used to create the plasma and induce the implantation of

ions. The desired background gases may include one or more of the following: hydrogen, argon, helium, nitrogen and/or methane or other hydrocarbon containing gas.

Figure 9 depicts a preferred method of implantation of polymeric material, wherein the polymeric component 66 of a blood pump is surrounded by conformal or non-conformal mesh 67. This said mesh 67 includes a plurality of holes or pores and is constructed of electrically conductive material.

In this embodiment, ions are induced to leave the plasma 68 and move towards the mesh 67, which acts as a target or an electrode. Preferably, the electrode is electrically conductive whilst the polymeric component to be treated is not. There is normally a region of relatively depleted ions and/or electrons, termed a plasma sheath, in close proximity to the electrode. In the plasma sheath 89, an electric field is present and this field accelerates ions entering from the plasma 68 so that ions cross the plasma sheath and gain energy from the electric field. Preferably, a portion of these ions travelling pathway 72 miss the target or electrode and pass through the plurality of holes or pores. These ions, which travel at high velocity, impact into the outer surface of the polymeric component 66.

Preferably, the component 66 may be rotated within the mesh 67 so as to expose all outer surfaces of the polymeric component 66. This rotation may be achieved by the use of a mount apparatus to which the component is attached or by rotating mesh 67 and allowing component 66 to freely tumble within the mesh 67. Additionally, the mesh 67 may be rotated, so as to allow the position of said holes to change in respect of the polymeric component 66. The effect of rotating the conformal mesh 67 may be that the resulting ion implantation may be relatively evenly distributed.

In a further embodiment, depicted in figure 10, a mesh 80 surrounds a polymeric component 78 in preferably a non-conformal manner. The mesh 80 may be oscillated and/or rotated so that that the work piece tumbles across the mesh and thereby provide relatively even coverage of ions entering the surface of the polymeric component 78.

A relatively high voltage is applied to the mesh 80 by means of a rotating high voltage feed-through 81 and this feed-through may be in turn connected to a power supply 82. The ions may travel through the gas background by paths 79. The mean free path of the

ions in the gas may be adjusted so that it may be relative to the distance travelled through the mesh 80 to the polymeric component 78. Preferably, this adjustment may be achieved by mechanical adjustment of the distances between the mesh 80, polymeric component 78 and the background gas. Additionally, the choice of background gas may be useful, for purposes of said adjustment.

A further preferred embodiment as depicted in figure 11. This embodiment differs from the previous embodiment depicted in Figure 10 in that a mesh 86 may be stationary and a polymeric component 83, to be treated, may be instead rotated or oscillated inside said mesh 86. This rotation and/or oscillation may be achieved by rotating and/or oscillating a support shaft 85, which is preferably connected to the polymeric component 83 through a hole (not shown in figure 11) in the mesh 86. The support shaft 85 preferably does not connect with the high voltage feed through 87 or the power supply 88.

In figure 11, the mesh is preferably able to carry a pulsed charge generated by the power supply 88 and supplied to the mesh by means of feedthrough 87. Preferably in this embodiment, neither the mesh 86, the feedthrough 87 nor the power supply 88 rotate or oscillate. Preferably, the charge applied to the mesh 86 is relatively high and may be approximately 2kV. Please note that as the ion implantation of the polymeric component 83 progresses, the implantation of ions generates a charge on the surface of the component 83. This charge may potentially block or impede further implantation. Therefore the charge must periodically be neutralized. The net effect of the pulsed charge on the electrode or mesh 86 is such that the surface charge on the polymeric component is periodically neutralized by the outside environment and this in turn allows continuing implantation to occur.

Figure 12 shows a graphical representation of a preferred method of the application of a pulsed charge to the electrode or mesh. This method may be useful for improving the rate of neutralization of the positive charge arising from the ions implanted into the polymeric component. As per the embodiment show in figure 12, a negative charge is periodically applied to the electrode. Generally, the charge is in the form of high voltage pulses, which are negative. This application has the effect of attracting ions into the component.

A further embodiment of a similar method is represented in figure 13. In this embodiment, positive and negative pulses are applied to the mesh or conductive electrode. These negative and positive pulses, in this embodiment, occur alternately. The negative pulses attract the ions to be implanted and the positive pulses attract electrons to neutralize the positive charge that builds up in the polymeric component. This process is generally termed a 'Bipolar' process.

Figure 14 depicts a further preferred method of implanting ions into the outer surface of a polymeric component 70. In this embodiment, a pulsed charge may be applied to an electrically conductive electrode 71 preferably mounted relative to the component 70 to allow ion implantation. Said pulsed charge induces ions to move at high velocity from a plasma background environment 69 towards the electrode 71. The polymeric component 70 to be implanted is positioned between the electrode 71 and the plasma 69. Thus, at least a proportion of ions move toward the electrode 71 and impact on the exposed outer surface of the component 70. Some of the pathways 73 by which the ions may travel are illustrated in figure 14.

Figure 15 depicts a further preferred method of implanting ions into the outer surface of a polymeric component 77. In this embodiment, the polymeric component is coated in a metal layer 76. This metal layer may be applied by spluttering or physical vapour evaporation deposition and is electrically conductive.

The metal layer 76 may form an electrode, when a pulsed charge is applied, and induces the movement of ions from the plasma 74 along the ion pathways, such as the pathways 75. At least a proportion of the ions impact on the exposed outer surface of component 77. Please note that it is preferable that the metal layer 76 is thin enough so as to allow ions through the layer 76 and impact into the polymeric component 77.

The metal layer 76 may be a relatively thin metal film. The thickness of said metal film is preferably carefully controlled so that the energy loss experienced by the ions, when passing through the electrode, is sufficiently small that the implantation depth is not compromised excessively.

Various additional modifications are possible within the scope of the foregoing specification and accompanying drawings without departing from the scope of the invention.

Aspects of the Invention

The following paragraphs define some aspects of the present invention:

1. An implantable rotary blood pump including an impeller rotatable within a housing by an electric motor, characterised in that at least a portion of said impeller is made of a polymeric material.

2. An implantable rotary blood pump as defined in paragraph 1, wherein said impeller includes at least one permanent magnet at least partially embedded within said polymeric material; and a barrier is disposed between said polymeric material and said magnet.

3. An implantable rotary blood pump as defined in paragraph 2, wherein said barrier is a layer of non-biotoxic material.

4. An implantable rotary blood pump as defined in paragraph 3, wherein said non-biotoxic material is any one of a metal, metallic compound or Parylene™.

5. An implantable rotary blood pump as defined in paragraph 1, wherein at least one surface of said impeller is made of said polymeric material and said surface is subjected to ion deposition and/or implantation.

6. An implantable rotary blood pump as defined in paragraph 4, wherein said ion deposition and/or implantation occur in a gas plasma environment.

7. An implantable rotary blood pump as defined in paragraph 6, wherein the gas in said gas plasma environment is any of hydrogen, argon, helium, oxygen, nitrogen, methane or a hydrocarbon gas.

8. An implantable rotary blood pump as defined in paragraphs 5 to 7, wherein said surface is partially coated with carbon.

9. An implantable rotary blood pump as defined in any one of paragraphs 5 to 8, wherein said surface is at least partially coated with a diamond-like coating.

10. An implantable rotary blood pump as defined in any one of paragraphs 1 to 9, wherein said polymeric material includes polyetheretherketone.

11. An implantable rotary blood pump as defined in any one of paragraphs 1 to 9 wherein at least a portion of said housing is made of polymeric material.

12. An implantable rotary blood pump as defined in any one of paragraphs 1 to 11, wherein said polymeric material includes a pharmaceutical or similar chemical agent.

13. An implantable rotary blood pump as defined in paragraph 10, wherein said pharmaceutical or similar chemical agent is slowly released or eluted.

14. An implantable rotary blood pump as defined in paragraphs 12 or 13, wherein said agent is an anti-coagulant and/or antimicrobial agent.

15. An implantable rotary blood pump as defined in any one of paragraphs 1 to 14 wherein said polymeric material is coated with a polymer phospholipid or a metal.

16. An implantable rotary blood pump as defined in any one of paragraphs 1 to 5, wherein said impeller or housing are constructed by injection moulding.

17. An implantable rotary blood pump as defined in any one of paragraphs 1 to 16, wherein said impeller is suspended within said housing by hydrodynamic thrust forces generated by relative movement between said impeller and said housing and said impeller having a hydrodynamic bearing.

18. A method of treatment of polymeric components for use in an implantable rotary blood pump, said method comprising the steps of:

(i) charging an electrode to attract ions from a plasma; and

(ii) said polymeric component positioned relative to said plasma and said electrode so as to create ion implantation of at least a region on the surface of said polymeric component.

19. A method as defined in paragraph 18 wherein during step (ii) said polymeric component is rotated to allow ion implantation to take place on substantially all surfaces of the polymeric component.

20. The method of either paragraphs 18 or 19, wherein said electrode includes a mesh configuration, which includes a plurality of holes.

21. The method of paragraphs 20, wherein said mesh configuration is rotated to allow relatively even ion implantation through positional movement of the said holes with respect to the polymeric component.

22. The method of paragraph 18, wherein at least a portion of said polymeric component is positioned between said plasma and said electrode.

23. The method of either paragraphs 18 or 19, wherein said electrode includes a thin metal layer deposited over the outer surfaces of said polymeric component.

24. The method of paragraph 23, wherein said thin layer is deposited by sputtering or vacuum evaporation techniques.

25. The method of any one of paragraphs 18 to 24, wherein said plasma is within a gas plasma environment.

26. The method of paragraph 25, wherein the gas of said gas plasma environment includes any of hydrogen, argon, helium, oxygen, nitrogen, methane or hydrocarbon gas.

27. The method of any one of paragraphs 18 to 26, wherein said treated polymer component includes chemically modified polymers.

Dated this 31st day of October 2003

VENTRACOR LIMITED

By:

HODGKINSON AND McINNES

Patent Attorneys for the Applicant

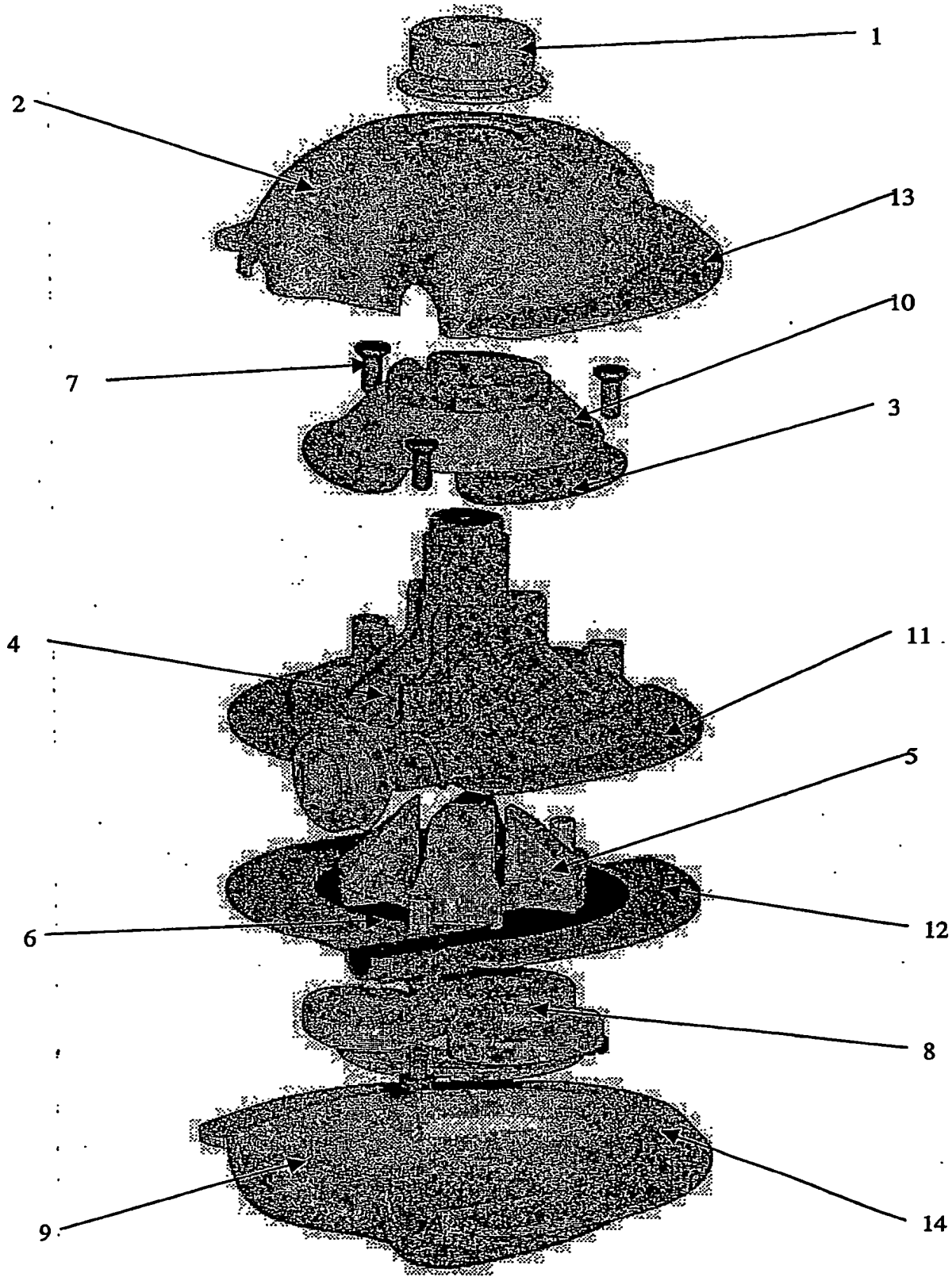
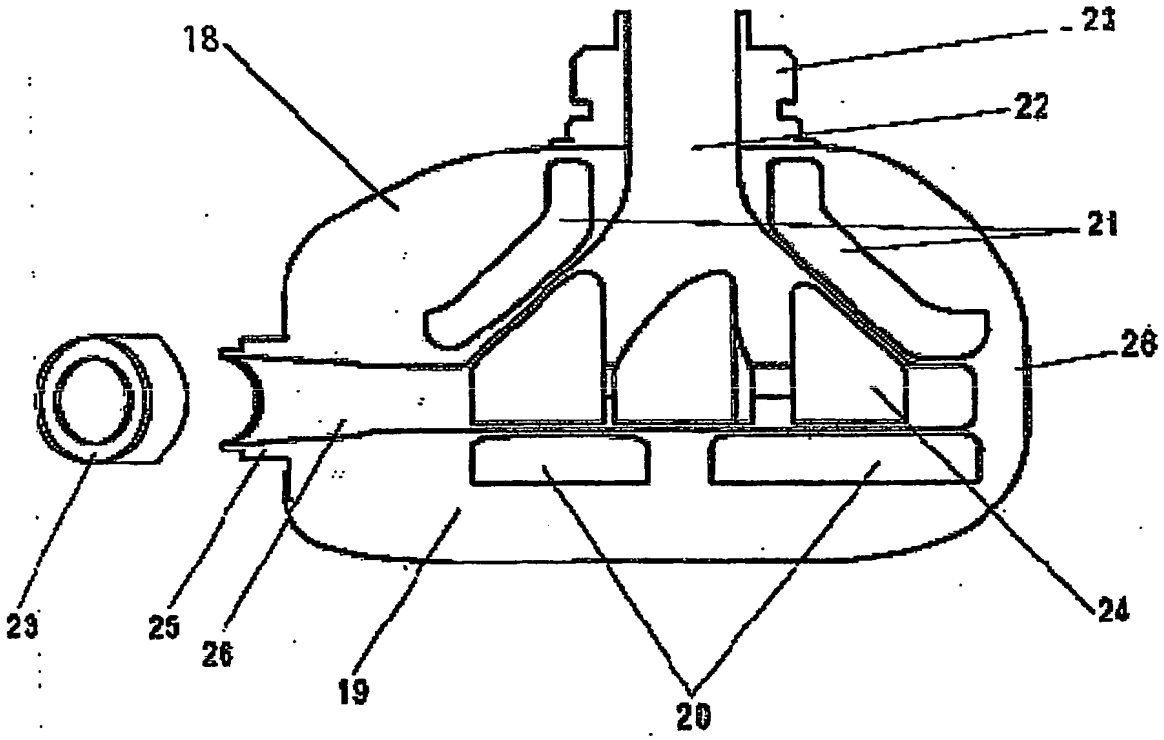


Figure 1



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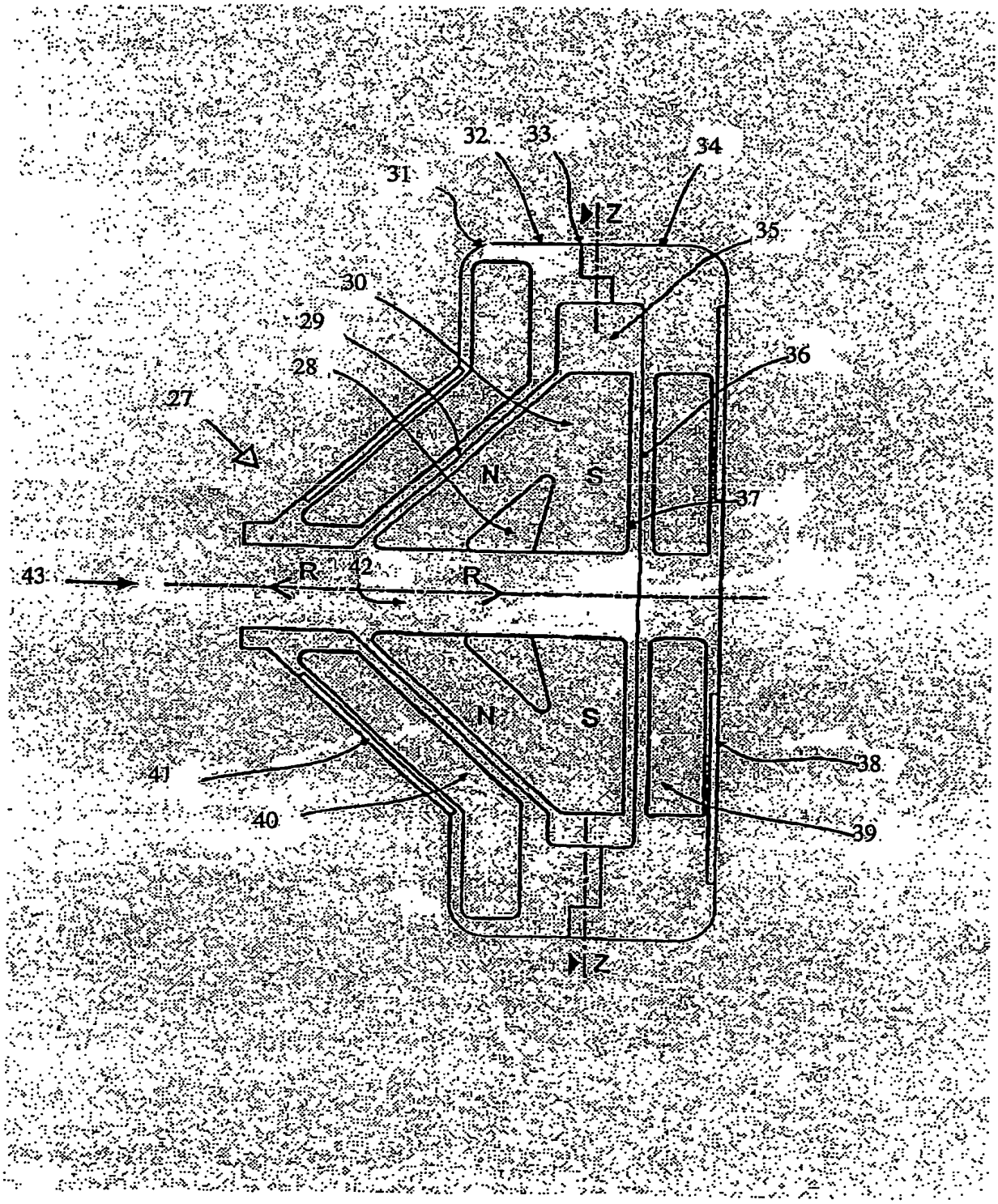

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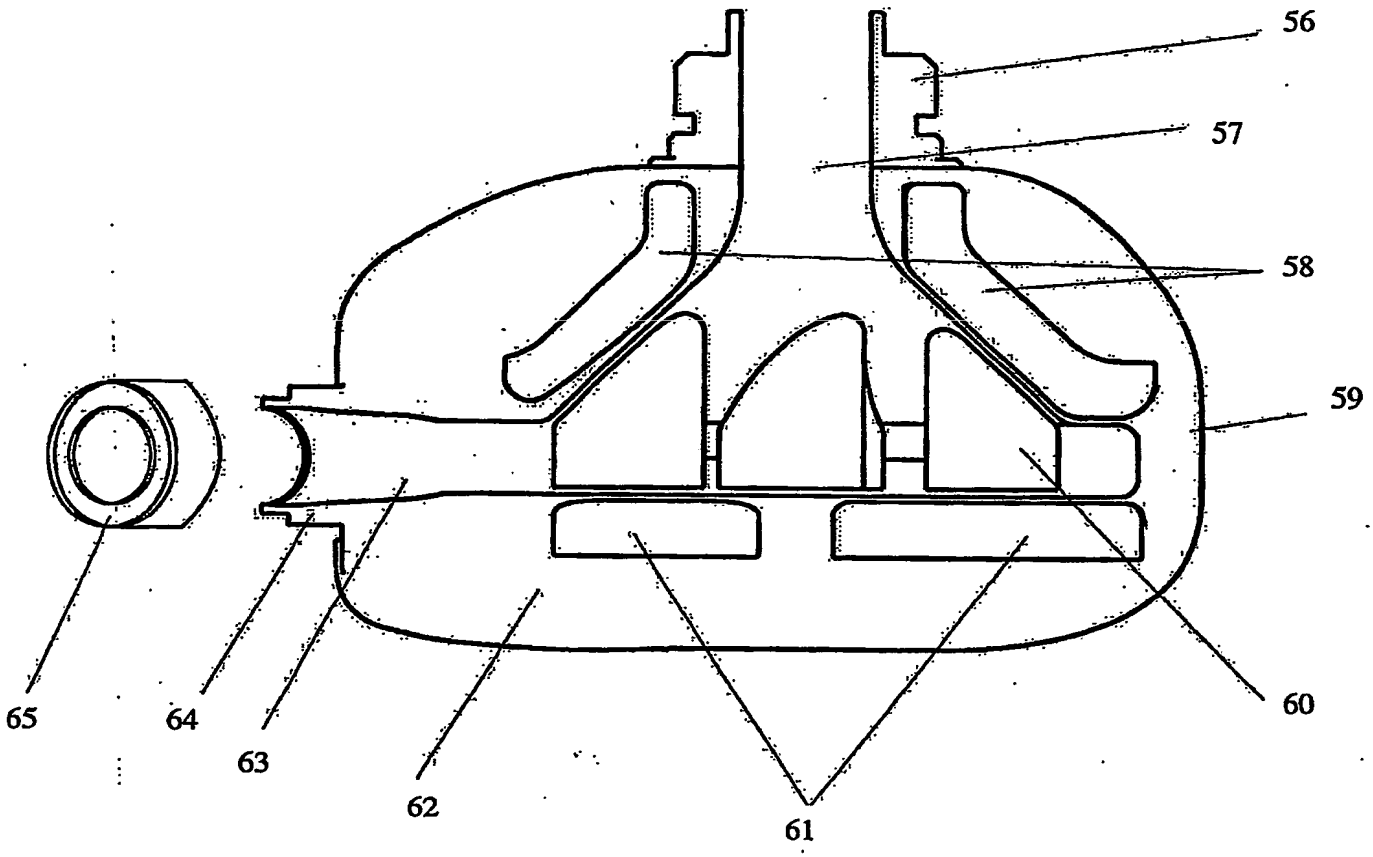

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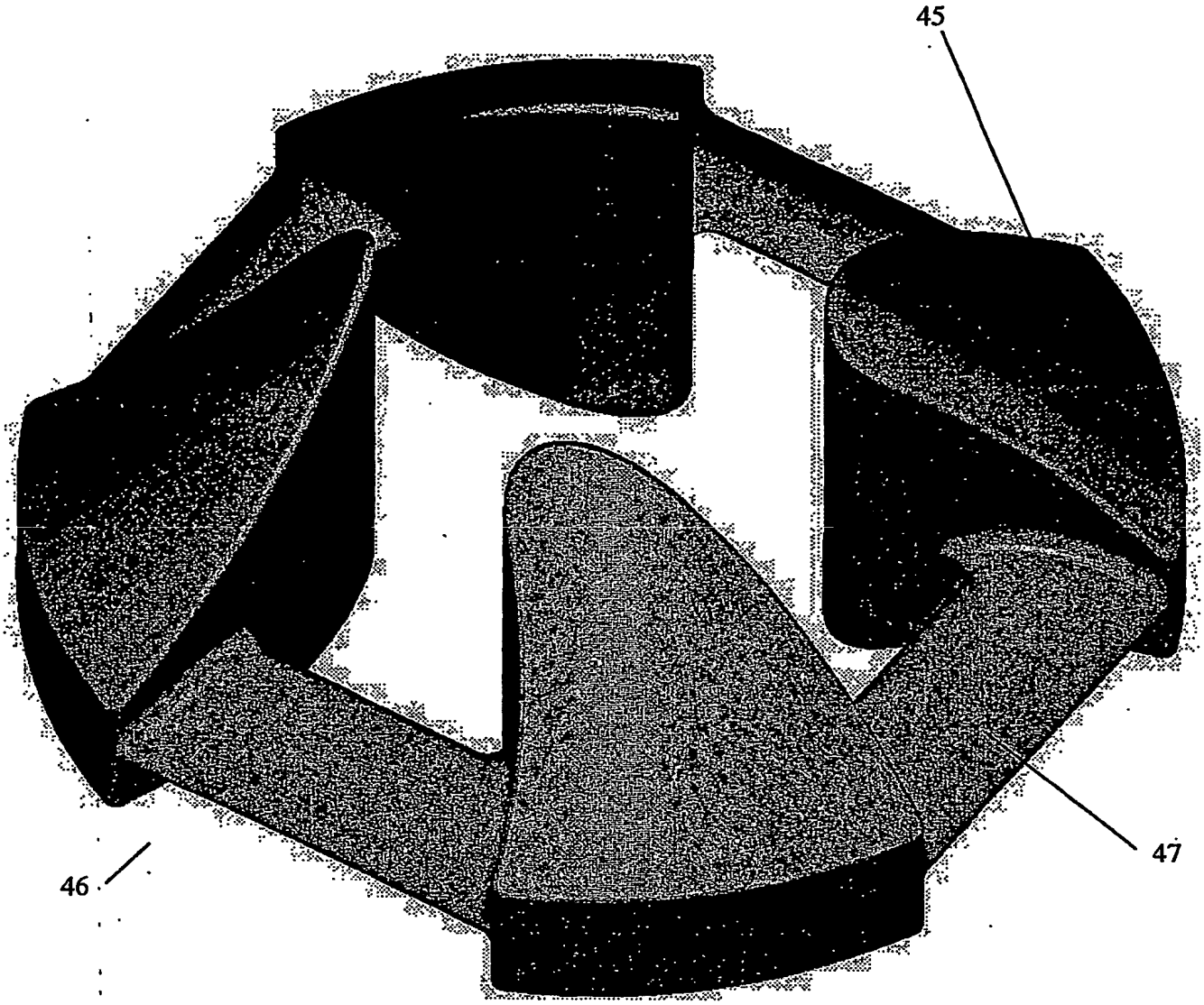

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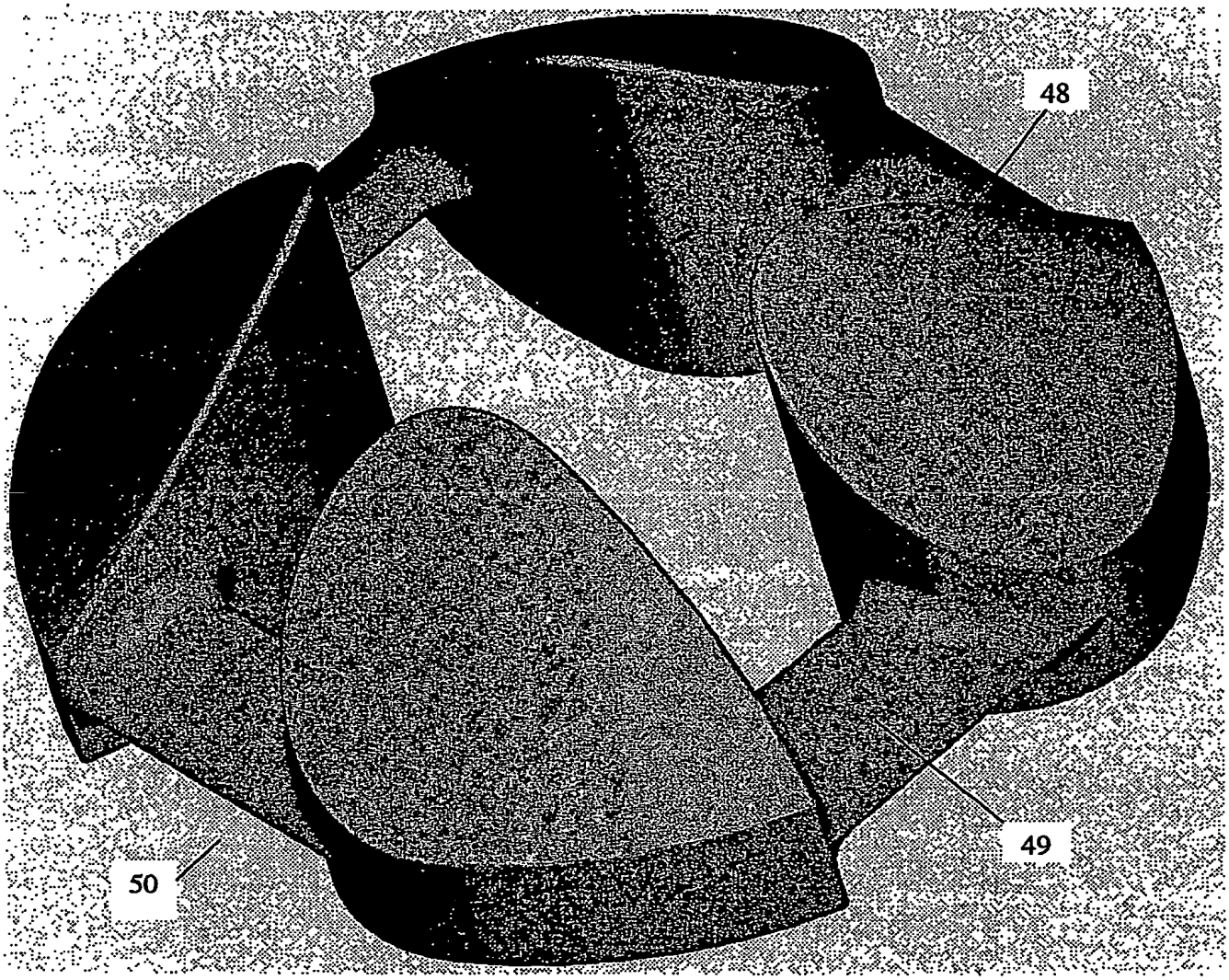
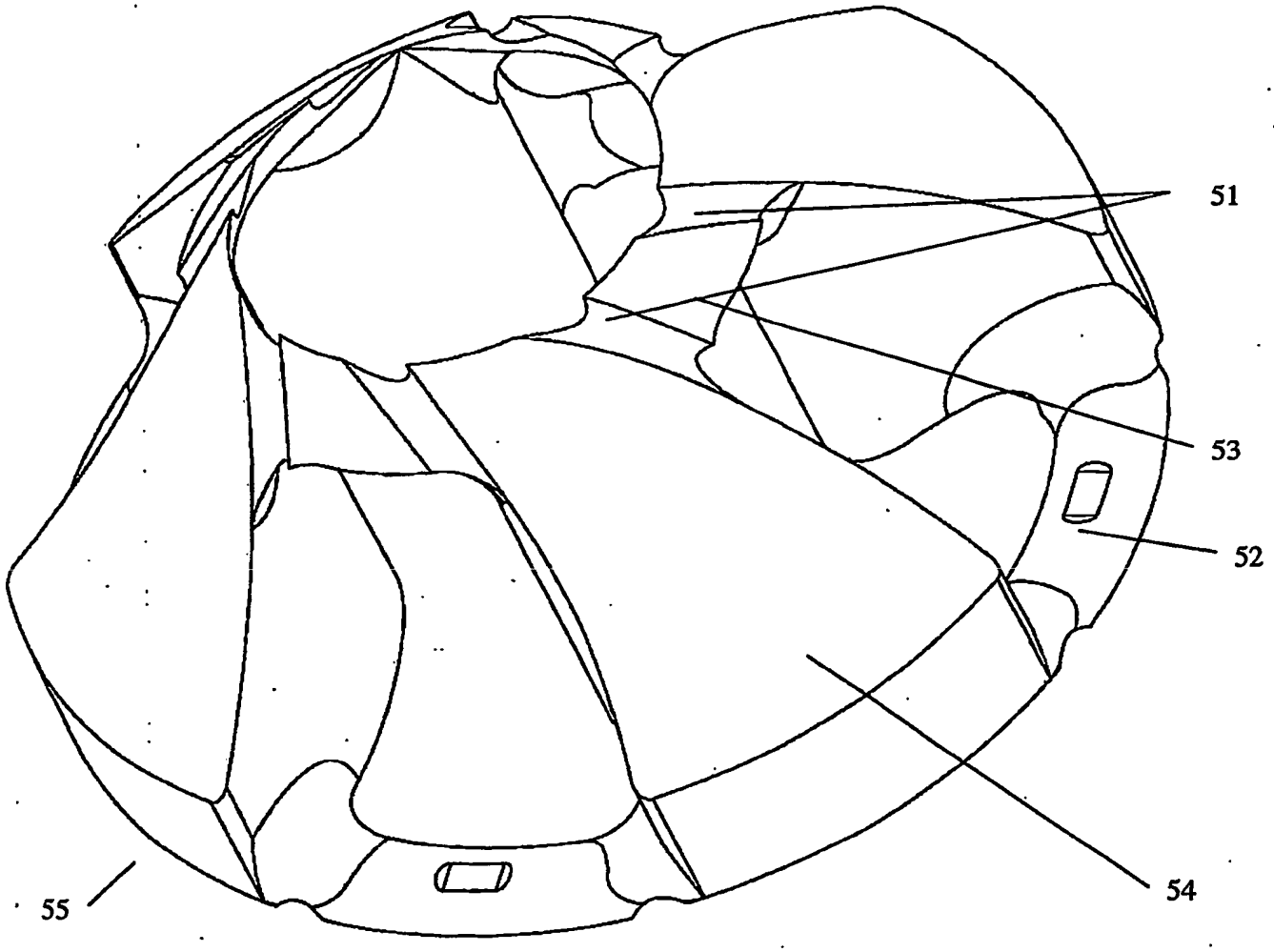


Figure 6



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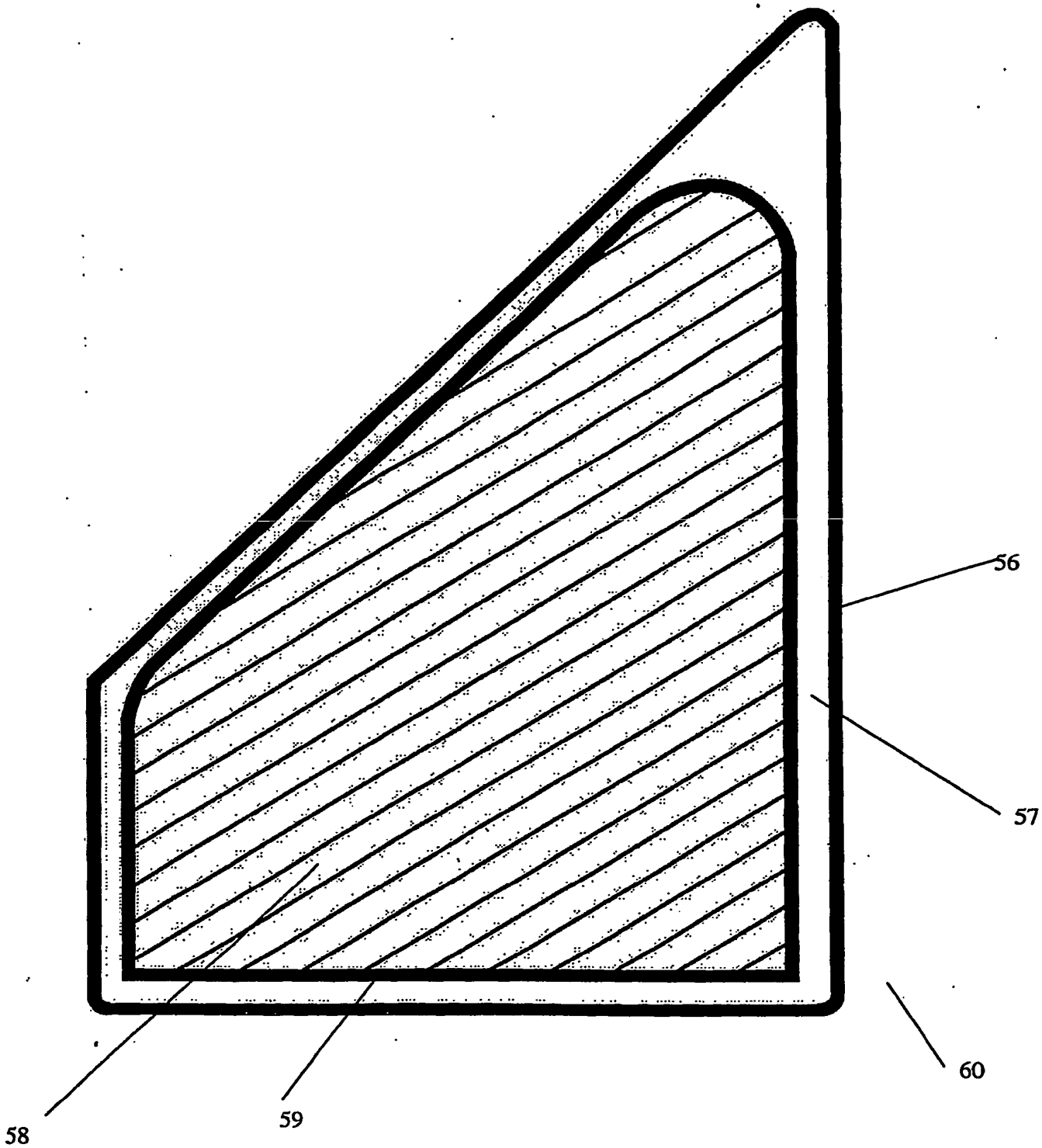

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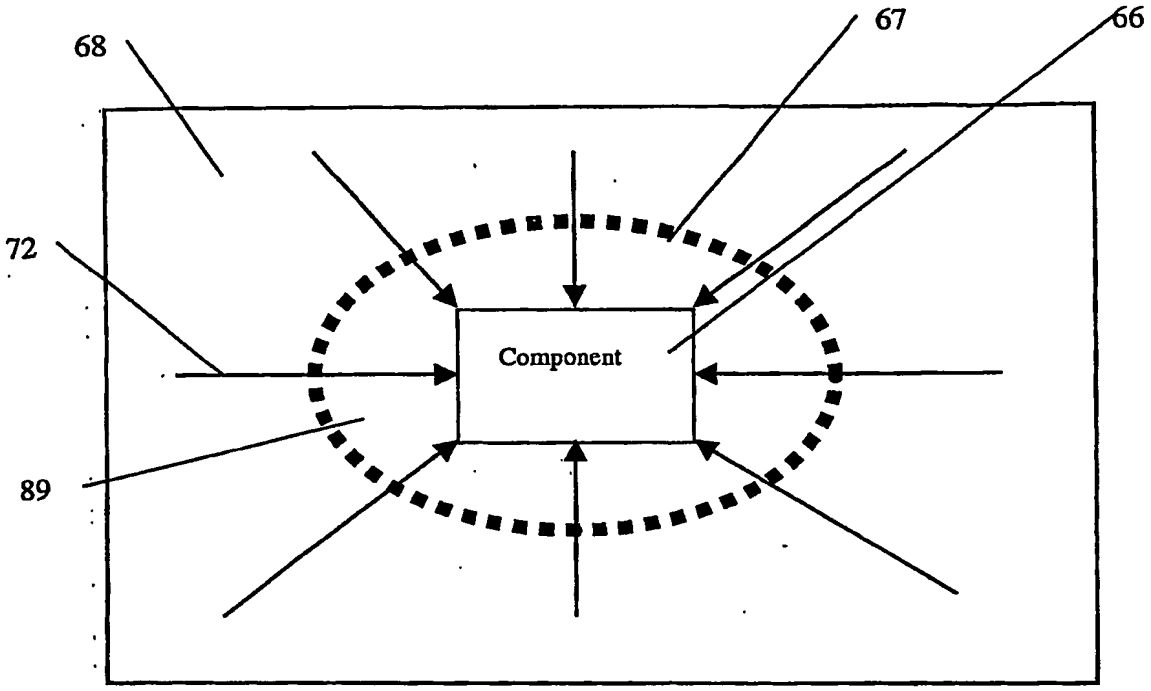

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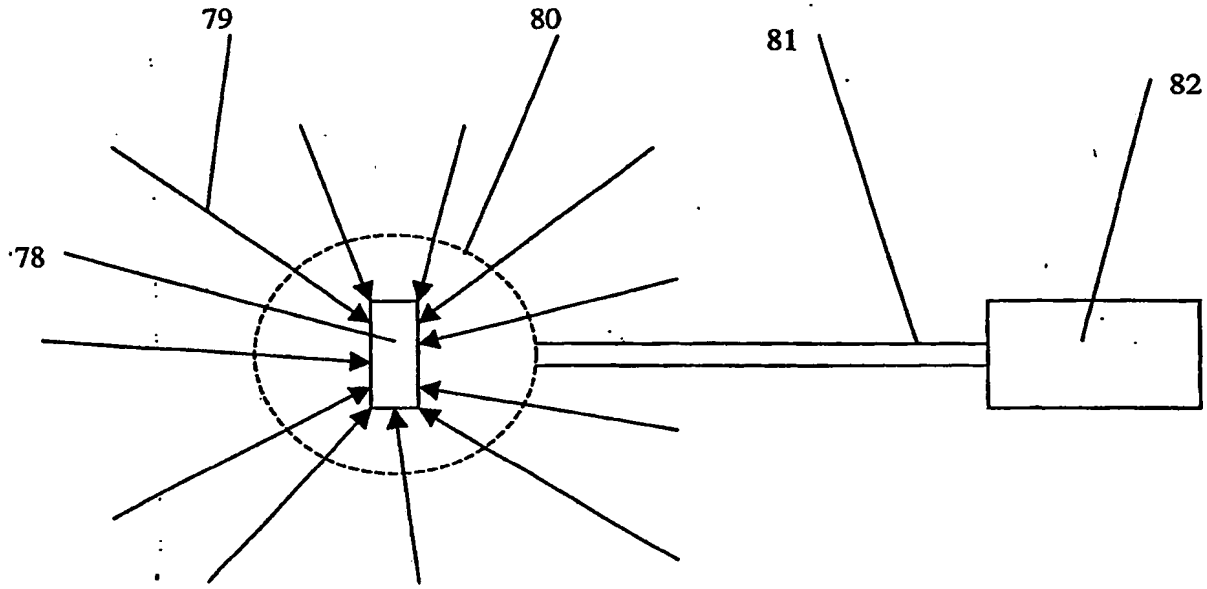

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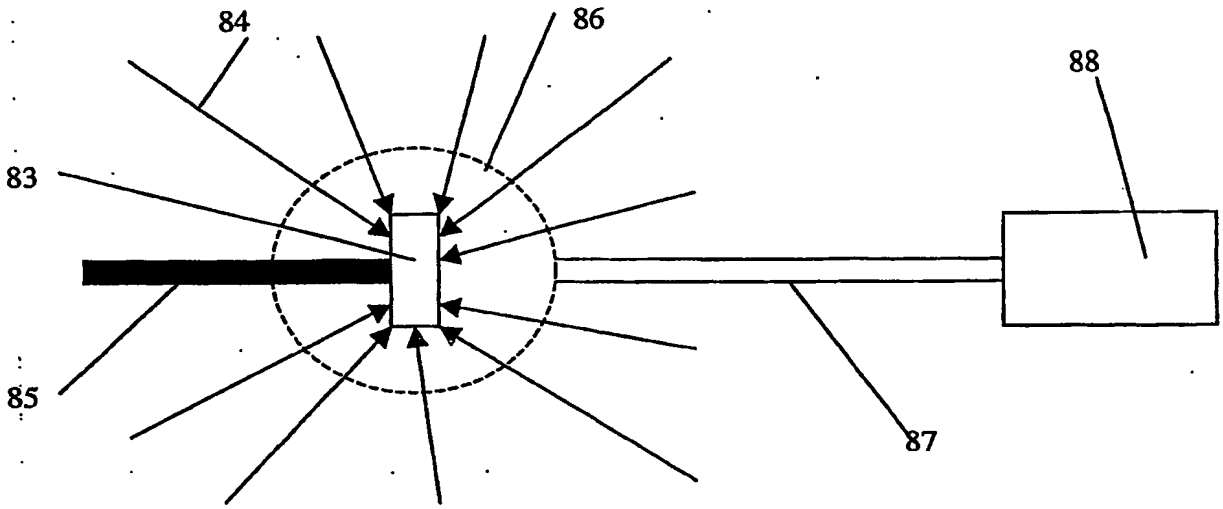

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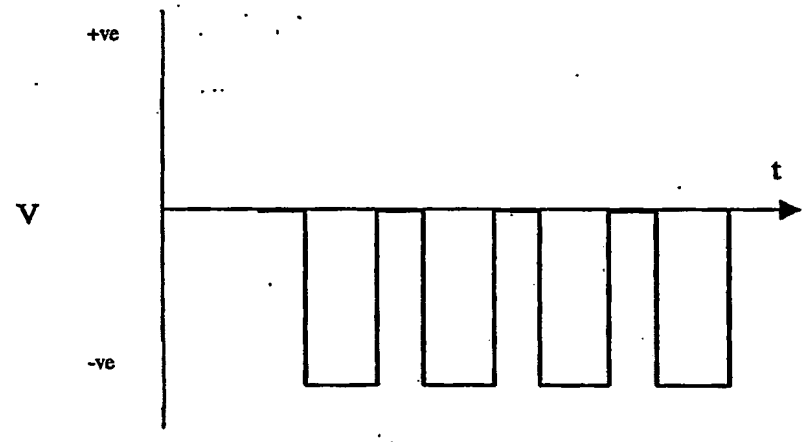

Figure 12

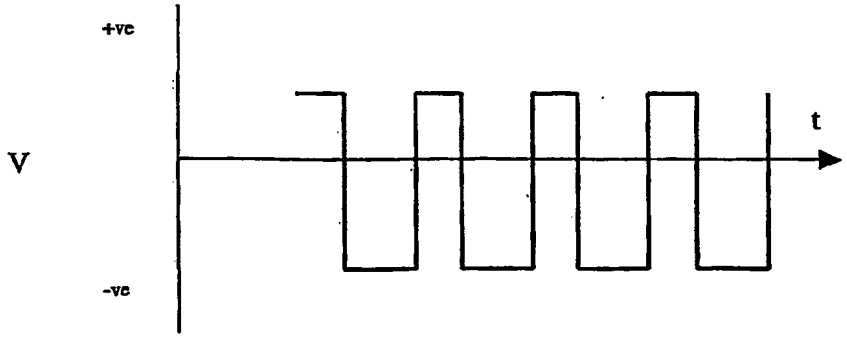

Figure 13

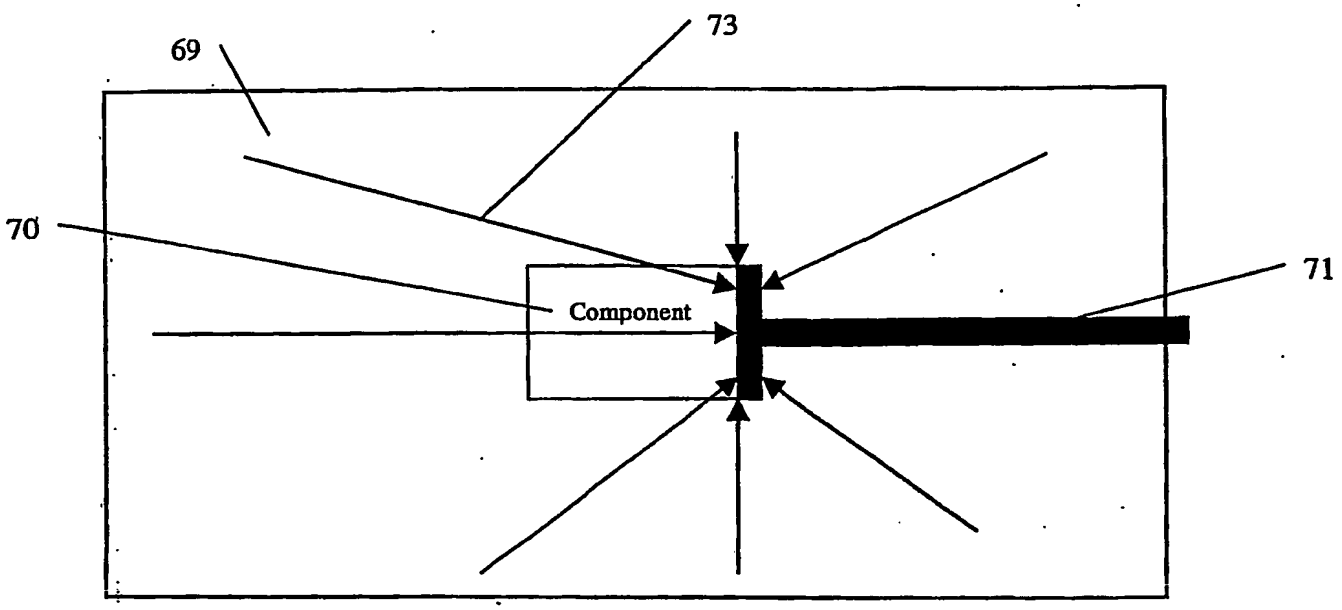

Figure 14

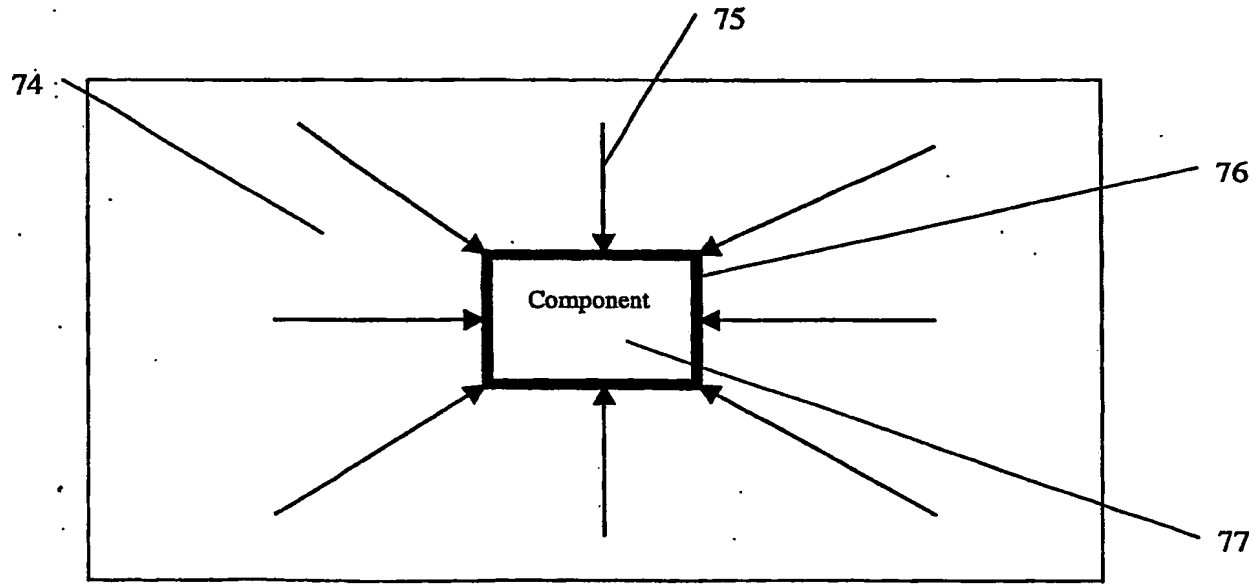

Figure 15

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